UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER
PURSUANT TO RULE 13A-16 OR 15D-16 UNDER
THE SECURITIES EXCHANGE ACT OF 1934

For the month of January 2024

Commission File Number: 001-38283

InflaRx N.V.

(Translation of registrant's name into English)

Winzerlaer Str. 2
07745 Jena, Germany
(Address of principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F ☐ Form 40-F ☐

EXPLANATORY NOTE

On January 4, 2024, InflaRx N.V. (the "Company") issued a press release titled "InflaRx Announces Positive Topline Results from the Multiple Ascending Dose (MAD) Phase I Study with C5aR Inhibitor INF904." A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated by reference herein.

In connection with such announcement, also on January 4, 2024, the Company hosted a conference call and presented its corporate presentation. A copy of the corporate presentation is attached hereto as Exhibit 99.2 and is incorporated by reference herein.

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release, dated January 4, 2024
99.2	Corporate Presentation, dated January 4, 2024

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

INFLARX N.V.

Date: January 4, 2024

By: /s/ Niels Riedemann
Name: Niels Riedemann
Title: Chief Executive Officer

Exhibit 99.1

InflaRx Announces Positive Topline Results from the Multiple Ascending Dose (MAD) Phase I Study with C5aR Inhibitor INF904

- MAD pharmacokinetic and pharmacodynamic data support best-in-class potential of INF904 over tested dose range of 30 mg once per day (QD) to 90 mg twice per day (BID) for 14 days:
  - Achieved ≥90% blockade of C5a-induced neutrophil activation over 14-day dosing period
  - Achieved favorable concentration-time profiles with target exposures of therapeutic potential
  - Well tolerated with no safety signals of concern over entire dose range
- Company to advance INF904 into Phase II clinical development
- Company to host a conference call today, January 4, 2024 at 8:30 a.m. EST/14:30 CET

Jena, Germany, January 4, 2024 – InflaRx N.V. (Nasdaq: IFRX), a biotechnology company pioneering anti-inflammatory therapeutics targeting the complement system, announced today topline results from the multiple ascending dose (MAD) part of its randomized, double-blind, placebo-controlled Phase I trial for INF904, an orally administered low molecular weight C5aR inhibitor. The pharmacokinetic (PK) and pharmacodynamic (PD) parameters confirm the favorable data InflaRx reported recently from the single ascending dose (SAD) part of the study, which provides support for the best-in-class potential of this drug candidate. INF904 was well tolerated and there were no adverse safety events of concern after repeated dosing in participants over the entire tested dose range.

In the MAD part of the randomized, double-blind, placebo-controlled Phase I trial, 24 participants received multiple doses of INF904 for 14 days of either 30 mg once per day (QD), 30 mg twice per day (BID) or 90 mg BID. The study's primary objective was to evaluate the safety and tolerability of repeated dosing. Several PK parameters were analyzed as secondary endpoints, and the effect of the dosing scheme on C5a-induced neutrophil activation in blood samples from the participants was also explored in an ex vivo assay.

"We are very pleased that the MAD part of the Phase I study exceeded the already compelling results from the SAD part of the study. The PK and PD profiles suggest that INF904 allows for highly effective inhibition of the C5a/C5aR pathway and that INF904 should enable consistent control of C5aR signaling in patients. In addition, we have the potential to apply a broad dose range up to high doses for the planned development of INF904 in chronic immune-inflammatory conditions," said Dr. Camilla Chong, MD, Chief Medical Officer of InflaRx. "We are excited to advance this highly promising oral C5aR inhibitor into Phase II clinical development."

The safety analysis of INF904 in the MAD part of the Phase I study demonstrated that it was well tolerated in participants over the entire dose range and resulted in no safety signals of concern. The overall percentage of adverse events (AEs) in INF904 treated participants was 77.8%, which was lower than the 83.3% observed in the placebo group. There were no serious or severe AEs observed at any dosing level.

Analysis of the PK profile showed that potential target $AUC_{0\text{-}12h}$, C_{max}, and trough values were achieved rapidly within 14 days of 30 mg BID dosing. INF904 exposure further increased proportionally with dosing up to 90 mg BID. These results were demonstrated even when participants ingested the drug in a fasted state, suggesting that food is not required to achieve potentially therapeutic drug levels.

Analysis of the PD profile showed that the blocking activity of C5a-induced neutrophil activation by INF904 reached equal to or above 90% over the 14-day dosing period for all tested doses in an ex vivo challenge assay where physiological and disease-relevant levels of C5a were added to blood samples provided by the trial participants.

InflaRx previously reported the data from the SAD part of the trial with 62 healthy volunteers in a press release and conference call. The SAD part showed a favorable dose-proportional systemic exposure with desired blocking activity (>90%) of C5a-induced neutrophil activation at disease-relevant C5a levels for doses of 30 mg to 240 mg 24 hours post-administration.

In parallel, InflaRx has progressed with the development of a commercially viable formulation of INF904 which the Company plans to introduce into Phase II development towards the end of 2024.

InflaRx is currently conducting additional required pre-clinical studies, including long-term chronic toxicology studies, to enable longer-term dosing of INF904 for chronic inflammatory diseases. InflaRx currently plans to initiate a short-term dosing Phase II study towards the end of 2024, followed by a longer-term dosing Phase II study in 2025. Further details of this clinical development plan with selection of indications will be announced in due course.

Conference call scheduled for today, January 4, 2024

InflaRx will host a conference call today, January 4, 2024 at 8:30 a.m. EST (14:30 CET) to provide more details about the announced topline results of the MAD part of its Phase I study of INF904 in healthy human subjects. To participate in the conference call, participants may pre-register here and will receive a dedicated link and dial-in details to easily and quickly access the call. A replay will be available on the InflaRx website in the Investors – Events & Presentations section after the live conference call has concluded.

InflaRx's management team will host investor and business meetings during JPM Week from January 8 to 11, 2024 in San Francisco, California.

About INF904

INF904 is an orally administered small molecule inhibitor of C5a-induced signaling via the receptor C5aR. INF904 showed anti-inflammatory therapeutic effects in several pre-clinical disease models. Further, in contrast to the marketed C5aR inhibitor, in vitro experiments demonstrated that INF904 has minimal inhibition of the cytochrome P450 3A4/5 (CYP3A4/5) enzymes, which play an important role in the metabolism of a variety of metabolites and drugs, including glucocorticoids. Reported results from a first-in-human study demonstrated that INF904 is well tolerated in treated subjects and exhibits no safety signals of concern in single doses ranging from 3 mg to 240 mg or multiple doses ranging from 30 mg once per day (QD) to 90 mg twice per day (BID) for 14 days. Pharmacokinetic / pharmacodynamic data support best-in-class potential of INF904 with a ≥90% blockade of C5a-induced neutrophil activation achieved over the 14-day dosing period. InflaRx plans to bring INF904 into clinical Phase II development towards the end of 2024.

About InflaRx

InflaRx GmbH (Germany) and InflaRx Pharmaceuticals Inc. (USA) are wholly owned subsidiaries of InflaRx N.V. (together, InflaRx).

InflaRx (Nasdaq: IFRX) is a biotechnology company pioneering anti-inflammatory therapeutics by applying its proprietary anti-C5a and anti-C5aR technologies to discover, develop and commercialize highly potent and specific inhibitors of the complement activation factor C5a and its receptor C5aR. C5a is a powerful inflammatory mediator involved in the progression of a wide variety of inflammatory diseases. InflaRx's lead product candidate, vilobelimab, is a novel, intravenously delivered, first-in-class, anti-C5a monoclonal antibody that selectively binds to free C5a and has demonstrated disease-modifying clinical activity and tolerability in multiple clinical studies in different indications. InflaRx was founded in 2007, and the group has offices and subsidiaries in Jena and Munich, Germany, as well as Ann Arbor, MI, USA. For further information, please visit www.inflarx.com.

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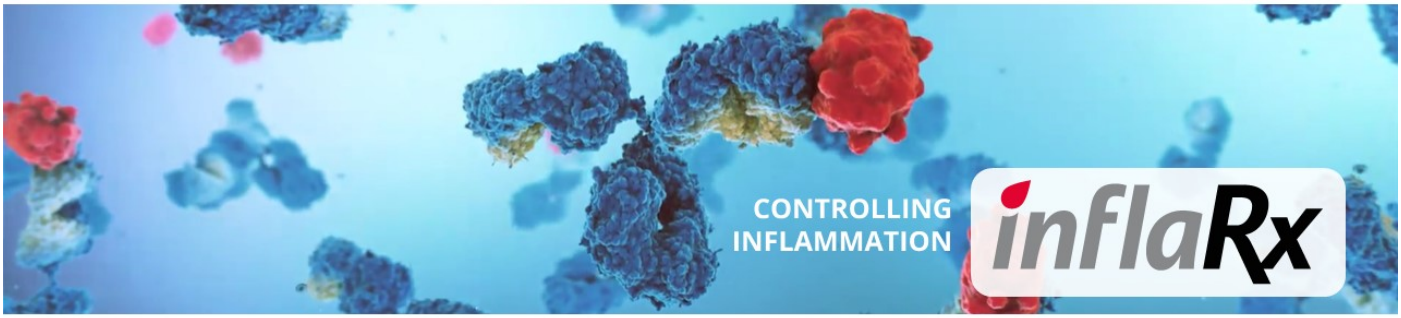
FORWARD-LOOKING STATEMENTS

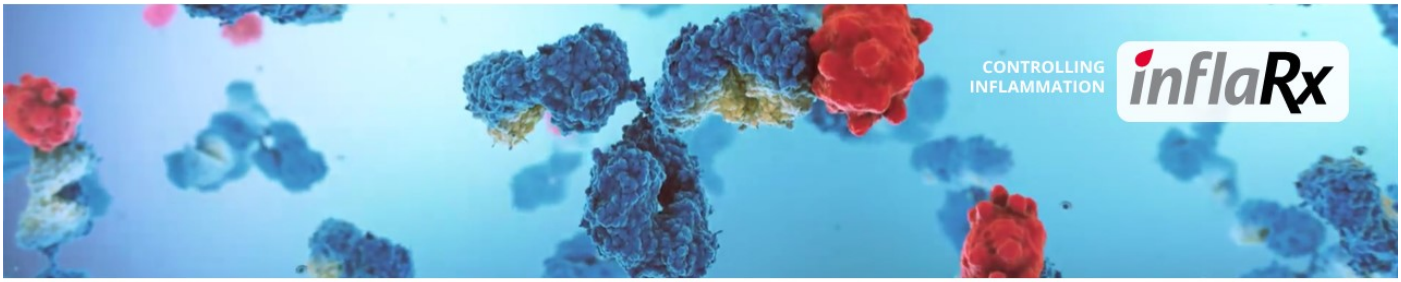
This press release contains forward-looking statements. All statements other than statements of historical fact are forward-looking statements, which are often indicated by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “estimate,” “believe,” “predict,” “potential” or “continue,” among others. Forward-looking statements appear in a number of places throughout this release and may include statements regarding our intentions, beliefs, projections, outlook, analyses and current expectations concerning, among other things, the receptiveness of Gohibic (vilobelimab) as a treatment for COVID-19 by COVID-19 patients and U.S. hospitals and related treatment recommendations by medical/healthcare institutes and other third-party organizations, our ability to successfully commercialize and the receptiveness of Gohibic (vilobelimab) as a treatment for COVID-19 by COVID-19 patients and U.S. hospitals or our other product candidates; our expectations regarding the size of the patient populations for, market opportunity for, coverage and reimbursement for, estimated returns and return accruals for, and clinical utility of Gohibic (vilobelimab) in its approved or authorized indication or for vilobelimab and any other product candidates, under an Emergency Use Authorization and in the future if approved for commercial use in the United States or elsewhere; the success of our future clinical trials for vilobelimab’s treatment of COVID-19 and other debilitating or life-threatening inflammatory indications, including pyoderma gangrenosum, and any other product candidates, including INF904, and whether such clinical results will reflect results seen in previously conducted pre-clinical studies and clinical trials; the timing, progress and results of pre-clinical studies and clinical trials of our product candidates and statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available, the costs of such trials and our research and development programs generally; our interactions with regulators regarding the results of clinical trials and potential regulatory approval pathways, including related to our Marketing Authorization Application submission for vilobelimab and our biologics license application submission for Gohibic (vilobelimab), and our ability to obtain and maintain full regulatory approval of vilobelimab or Gohibic (vilobelimab) for any indication; whether the U.S. Food and Drug Administration, the European Medicines Agency or any comparable foreign regulatory authority will accept or agree with the number, design, size, conduct or implementation of our clinical trials, including any proposed primary or secondary endpoints for such trials; our expectations regarding the scope of any approved indication for vilobelimab; our ability to leverage our proprietary anti-C5a and C5aR technologies to discover and develop therapies to treat complement-mediated autoimmune and inflammatory diseases; our ability to protect, maintain and enforce our intellectual property protection for vilobelimab and any other product candidates, and the scope of such protection; our manufacturing capabilities and strategy, including the scalability and cost of our manufacturing methods and processes and the optimization of our manufacturing methods and processes, and our ability to continue to rely on our existing third-party manufacturers and our ability to engage additional third-party manufacturers for our planned future clinical trials and for commercial supply of vilobelimab and for the finished product Gohibic (vilobelimab); our estimates of our expenses, ongoing losses, future revenue, capital requirements and our needs for or ability to obtain additional financing; our ability to defend against liability claims resulting from the testing of our product candidates in the clinic or, if approved, any commercial sales; if any of our product candidates obtain regulatory approval, our ability to comply with and satisfy ongoing obligations and continued regulatory overview; our ability to comply with enacted and future legislation in seeking marketing approval and commercialization; our future growth and ability to compete, which depends on our retaining key personnel and recruiting additional qualified personnel; and our competitive position and the development of and projections relating to our competitors in the development of C5a and C5aR inhibitors or our industry; and the risks, uncertainties and other factors described under the heading “Risk Factors” in our periodic filings with the U.S. Securities and Exchange Commission. These statements speak only as of the date of this press release and involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Given these risks, uncertainties and other factors, you should not place undue reliance on these forward-looking statements, and we assume no obligation to update these forward-looking statements, even if new information becomes available in the future, except as required by law.

Exhibit 99.2



INF904: TOPLINE RESULTS FROM PHASE I MAD STUDY

JANUARY 4, 2024



IMPORTANT NOTICE AND DISCLAIMER

This presentation has been prepared by InflaRx N.V. ("InflaRx" or the "Company"). This presentation is made for informational purposes only and does not constitute an offer to sell or a solicitation of an offer to buy securities. This presentation may not be relied upon in connection with the purchase or sale of any security and should not be construed as investment advice.

Forward-Looking Statements

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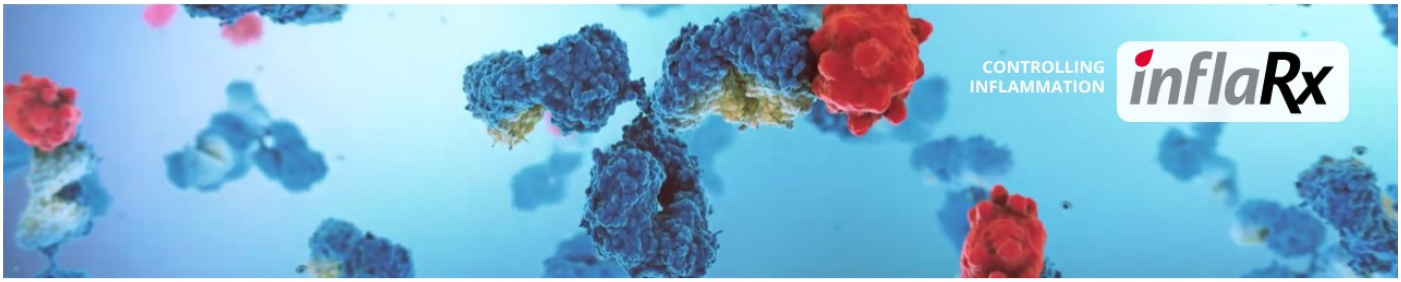

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Information and Sources

Certain information contained in this presentation relates to or is based on studies, publications, surveys and other data obtained from third-party sources and InflaRx's own internal estimates and research. While InflaRx believes these third-party sources to be reliable as of the date of this presentation, it has not independently verified, and makes no representation as to the adequacy, fairness, accuracy or completeness of, any information obtained from third-party sources. In addition, all of the market data included in this presentation involves a number of assumptions and limitations, and there can be no guarantee as to the accuracy or reliability of such assumptions. Further, while we believe our own internal research is reliable, such research has not been verified by any independent source.

Avacopan Data

We have not conducted a head-to-head comparison of Avacopan to INF904 in a clinical trial but have compared the published data for Avacopan to data from our Phase 1 clinical trial of INF904. For the purpose of conducting pre-clinical studies (hamster neutropenia study), we synthesized Avacopan and did a side-by-side comparison. While we believe this comparison to Avacopan to be useful and appropriate, the value of this and other comparisons to Avacopan in this presentation may be limited because they are not derived from a head-to-head trial and they are from trials that were conducted under different protocols at different sites and at different times. Without head-to-head data, we are unable to make comparative claims between INF904 and Avacopan.

About InflaRx

InflaRx GmbH (Germany) and InflaRx Pharmaceuticals Inc. (USA) are wholly owned subsidiaries of InflaRx N.V. (together, "InflaRx").

InflaRx (Nasdaq: IFRX) is a biotechnology company pioneering anti-inflammatory therapeutics by applying its proprietary anti-C5a and anti-C5aR technologies to discover, develop and commercialize first-in-class, potent and specific inhibitors of the complement activation factor C5a and its receptor C5aR. C5a is a powerful inflammatory mediator involved in the progression of a wide variety of inflammatory diseases. InflaRx's lead product candidate, vilobelimab, is a novel, intravenously delivered, first-in-class, anti-C5a monoclonal antibody that selectively binds to free C5a and has demonstrated disease-modifying clinical activity and tolerability in multiple clinical studies in different indications. InflaRx was founded in 2007, and the group has offices and subsidiaries in Jena and Munich, Germany, as well as Ann Arbor, MI, USA. For further information, please visit www.inflarx.com.

Speakers

Speaker

PROF. NIELS RIEDEMANN, M.D., PH.D.
Chief Executive Officer, Founder, InflaRx

CAMILLA CHONG, M.D.
Chief Medical Officer, InflaRx

Q&A

PROF. RENFENG GUO, M.D.
Chief Scientific Officer, Founder, InflaRx

THOMAS TAAPKEN, PH.D.
Chief Financial Officer, InflaRx

AGENDA

- BACKGROUND AND PRE-CLINICAL WORK
- STUDY DESIGN
- SAFETY OUTCOME
- PK OUTCOME
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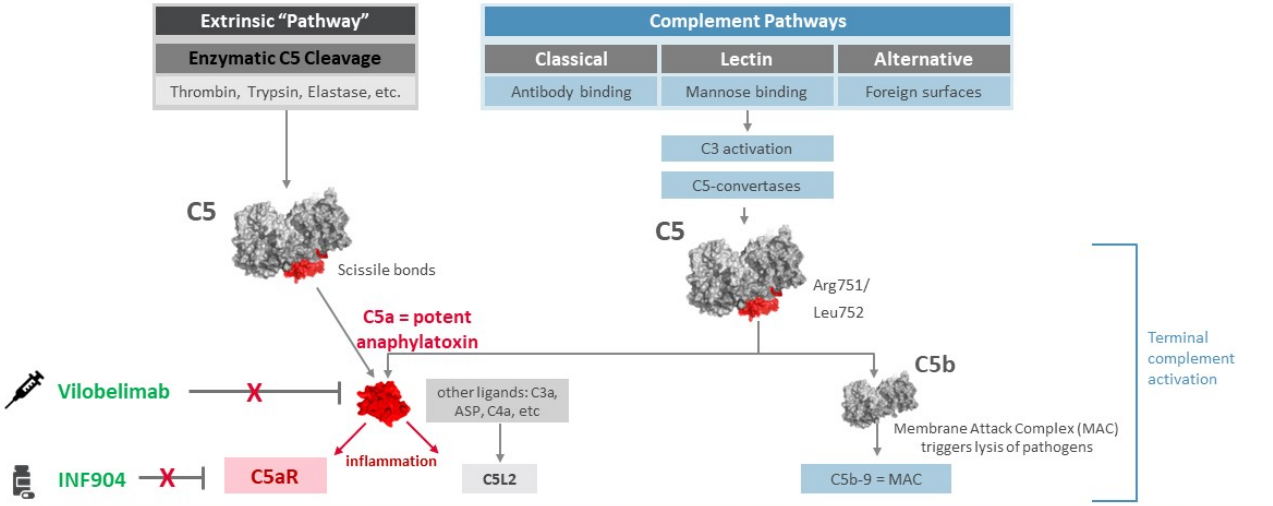
The Complement System and C5a Activation



The extrinsic pathway represents an additional route, outside of the known complement pathways, to cleave C5a from C5 --- C5a acts primarily through C5aR

C5aR is a Validated Drug Target for Inflammation

C5aR: a promising drug target

- C5aR, a G-protein-coupled receptor highly expressed on granulocytes and in epithelial cell, mediates the major pathophysiological effects of C5a.
- Blockade of C5aR showed strong anti-inflammatory effects in numerous pre-clinical disease models in both acute and chronic settings and in clinical research.
- C5aR antagonists are expected to be stand-alone or adjunct treatments for a variety of inflammatory disorders.
- One marketed drug candidate only, with a PK/PD profile which could be improved based on the published data of the Phase I clinical trial [a].

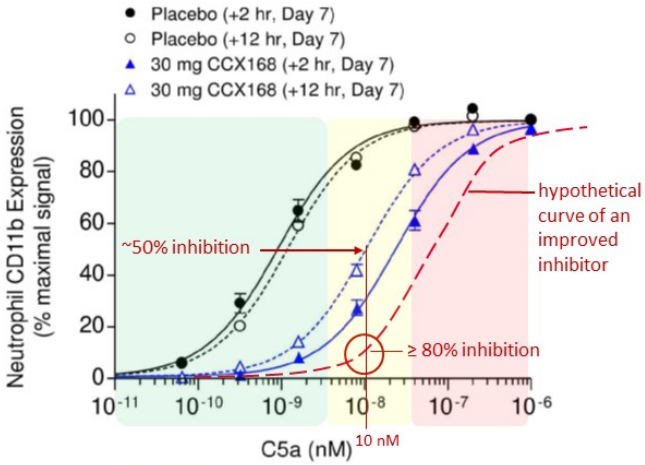
Role of C5aR in pre-clinical and clinical R&D

[a] *Bekker et al. 2016, PLOS ONE 11(10): E0164646*

Improvement of C5aR Inhibition

Properties of a best-in-class C5aR antagonist

- **Improved PK properties** with higher plasma trough level (>> 36 ng/mL) to achieve:
- **Improved blocking activity** in vivo in humans (>> 50% blocking at 10 nM C5a) **= significantly stronger inhibition of neutrophil activation at C5a levels known to be present in diseases.**
- **Improved drug strength** to allow fewer capsules per dosing and potentially less frequent dosing.



Modified from Bekker et al. (2016, PLoS One; 11(10): e0164646); CCX168 = Avacopan; whole blood ex vivo assay upon 7 days of 2 x qd dosing with Avacopan measuring up-regulation of CD11b on blood neutrophils upon challenge with addition of different levels of recombinant C5a. CD11b is a marker of neutrophil activation known to rise quickly upon interaction of C5a with the C5a receptor. Measurements were taken at 2 hr or 12h upon last dosing (on day 7) and then ex vivo challenge with different doses of C5a.

INF904: Pre-clinical Summary

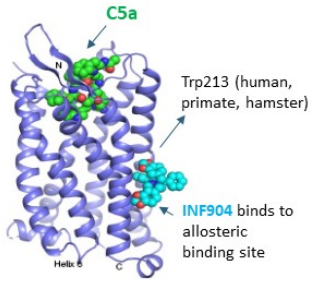
INF904 facts

- INF904 binds to a well-defined allosteric site in C5aR.
- INF904 has a novel molecular structure.
- US patent was issued in October 2021; national phases for other select countries (PCT).

Pre-clinical findings

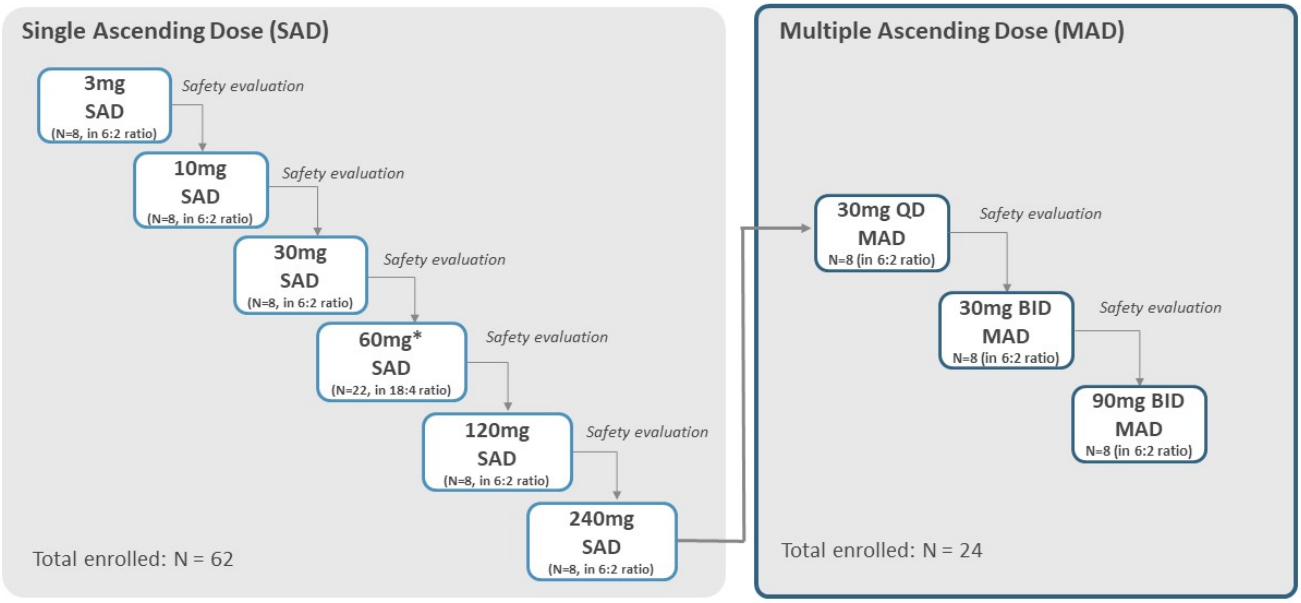
- **No obvious toxicity findings** even in the highest dose groups (rat and monkey; up to 300 mg/kg).
- **High in vitro potency** with a desired IC50 (<1nM) in calcium mobilization assay.
- **Higher plasma exposures** in several in vivo models when compared to Avacopan*.
- **Increased efficacy** in hamster neutropenia model when tested at equivalent dose with an Avacopan-like molecule*.
- **Therapeutic effects** in pre-clinical disease models (renal/peritonitis).

**InflaRx data on file. Avacopan synthesized based on the published structure and publicly available data.*



C5aR structure
(Source: Nathan Robertson, 2018 Nature)

INF904 Phase I Study Designs for SAD and MAD



Footnotes: N= participants per dosing cohort, Ratio for randomization is shown for INF904 : matching Placebo; *3 different capsule strengths tested in a cross-over design

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INF904 Phase I Study: Safety Results from MAD (and SAD) Part – Primary Objectives

SAD PART

- INF904 was found to be well tolerated and resulted in no signals of safety concern in single ascending doses ranging from 3 mg to 240 mg.
- Overall percentage of Adverse Events (AEs) in placebo group (85.7%) was higher than in active treated subjects (58.3%).
- AE severity: Mild: 78; Moderate: 9; Severe: 0.
- No Serious AE (SAE) reported at any dosing level.
- 1 moderate AE rated as possibly related to placebo (headache) and 2 mild AEs possibly related to study drug (diarrhea, flatulence).
- 1 subject in cohort 1.4 (60 mg) withdrawn for unrelated AE.

MAD PART

- INF904 was found to be well tolerated and resulted in no signals of safety concern in multiple ascending doses involving 30 mg QD, 30 mg BID and 90 mg BID.
- Overall percentage of AEs in placebo group was 83.3% compared to 77.8% in active treated subjects.
- AE severity: Mild: 52; Moderate: 5; Severe: 0.
- No SAE reported at any dosing level.
- 2 AEs, both of mild intensity and both in 1 subject (cohort 3.3/90 mg BID), rated as possibly related to study drug (diarrhea, flatulence).
- NO subject withdrawn from treatment/study.

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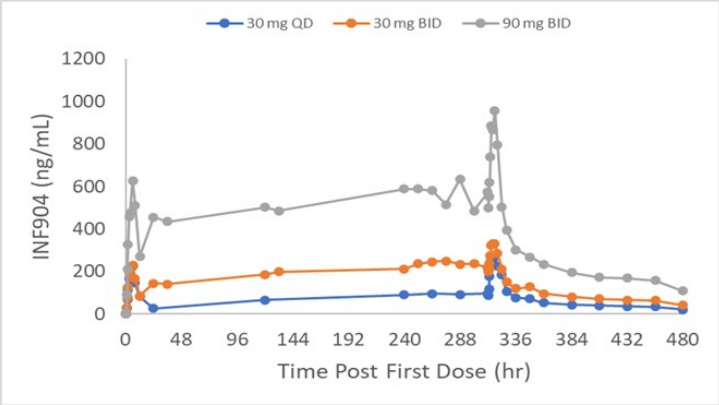
INF904 Phase I Study: PK Results from the Multiple Ascending Dose (MAD)



Dose (Regimen)	Day	C_{max} (ng/mL) ±SD	$AUC_{0\text{-}12hr}$ (ng x hr/mL) ± SD
30 mg QD	1	233 ± 79	1,615 ± 427
	14	284 ± 60	2,609 ± 792
30 mg BID	1	236 ± 97	1,742 ± 648
	14	356 ± 84	3,331 ± 821
90 mg BID	1	653 ± 217	4,815 ± 1,993
	14	1,028 ± 431	8,962 ± 4,247

QD: Once Daily Dosing, BID: Twice Daily Dosing

Results are based on interim data analysis

- INF904 dosing either once daily (QD) or twice daily (BID) exhibits favorable concentration-time profiles (after 14 days dosing)
- INF904 exposure is directly proportional to dose when comparing 30 mg BID versus the 90 mg BID regimens
- In BID regimen, accumulation observed (Day 1 to 14) for C_{max} and $AUC_{0\text{-}12hr}$ average ~ 1.3 and ~1.9-fold
- The first 90 mg dose achieves greater exposure than seen with Day 14 of the 30 mg BID dosing

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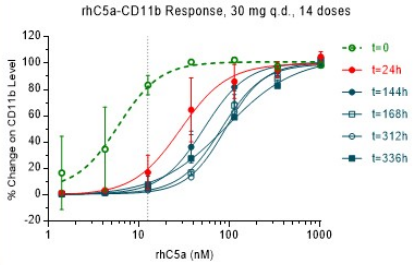
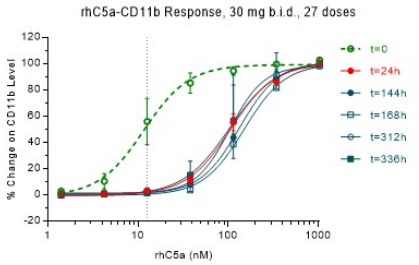
INF904 – Phase I: Whole Blood PD Analysis

Multiple Ascending Dose (MAD) Part

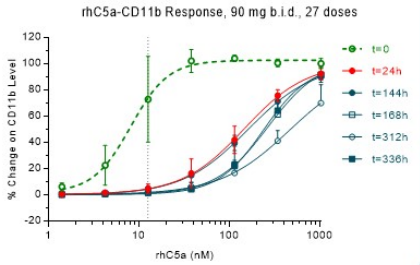
INF904: 30 mg QD



INF904: 30 mg BID



INF904: 90 mg BID



	Upon the stimulation with 12.6 nM rhC5a (levels observed in disease state)														
	24 h			144 h (Day 6)			168 h (Day 7)			312 h (Day 13)			336 h (Day 14)		
	30QD	30BID	90BID	30QD	30BID	90BID	30QD	30BID	90BID	30QD	30BID	90BID	30QD	30BID	90BID
Blockade (%)	80	94	90	93	95	94	95	97	97	96	92	97	90	95	97
EC_{50} (nM)	35.6	106.2	145.6	52.4	134.7	160	74.2	149.0	268.2	92.4	126.3	465.7	94.6	110.9	238

*EC_{50} (nM) is the half maximal effective C5a concentration

AGENDA

- BACKGROUND AND PRE-CLINICAL WORK
- STUDY DESIGN
- SAFETY OUTCOME
- PK OUTCOME
- PD OUTCOME
- SUMMARY

Summary

Topline Results from INF904 Phase I MAD Study

KEY OUTCOMES

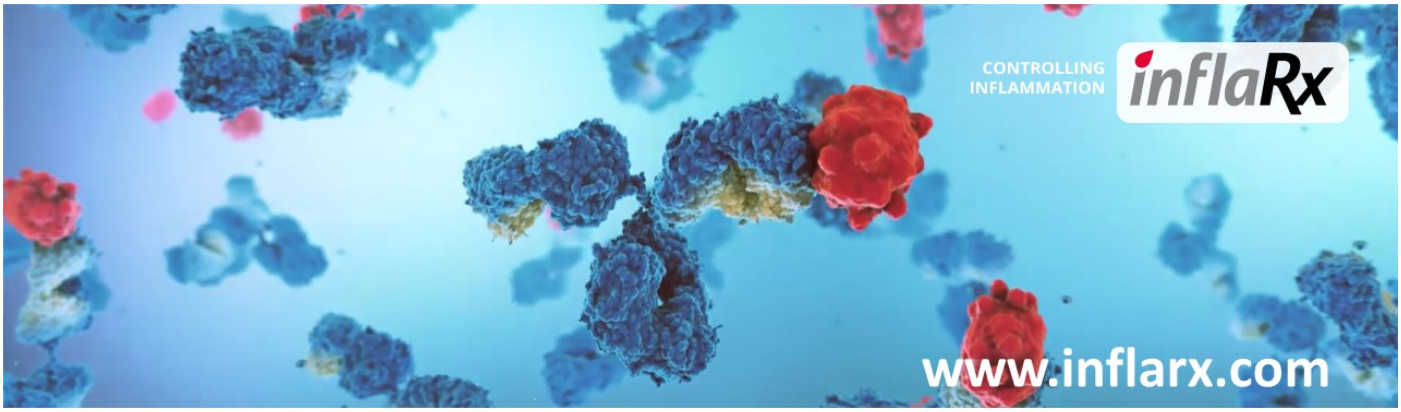
- INF904 was found to be well tolerated and with no signals of safety concern in multiple ascending doses ranging from 30mg QD – 90 mg BID.
- INF904 demonstrated a favorable PK profile with potential to achieve therapeutic exposures (AUC & Cmax) required in chronic immuno-inflammatory diseases.
- INF904 achieved ≥ 90% C5a blocking potential at C5a concentrations observed in human diseases.

INF904 confirms its best-in-class C5aR inhibitor potential within this Phase I multiple ascending dose study

INF904: Next Steps

Highlights

- Further drug development steps:
  - Introducing developed commercially viable formulation for Phase II clinical program
  - Complete long-term chronic toxicology studies
  - Planning for Phase II clinical studies to be initiated towards end of 2024



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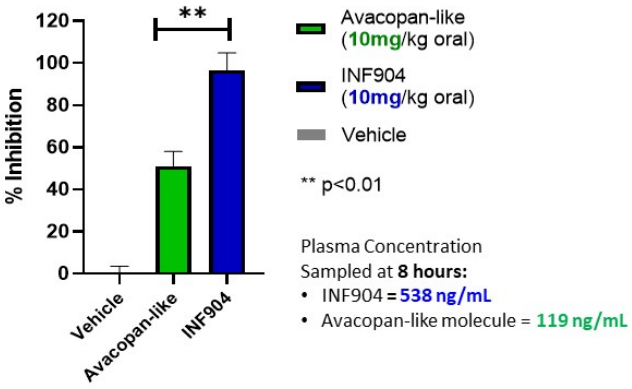
Appendix

PRE-CLINICAL DATA (PREVIOUSLY REPORTED)

SAD DATA (PREVIOUSLY REPORTED)

PRE-CLINICAL IN VIVO EFFICACY COMPARISON OF INF904 to AVACOPAN*

Inhibition of in vivo neutrophil activation by INF904 compared to Avacopan-like molecule*



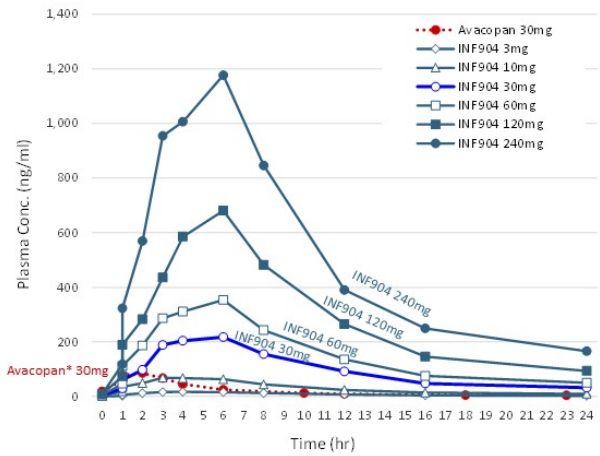
Experiment: Challenge of rodents with C5a leads to neutrophil activation and consequent adherence (sticking) of neutrophils to the endothelial cell wall of vessels = mimicking a neutropenia (vehicle). This effect can be completely inhibited when C5aR activation is blocked.

Outcome: INF904 is significantly superior to an identical dose of the Avacopan* in blocking C5aR, leading to an approximate doubling of neutrophil inhibition in vivo in this rodent model.

Note: INF904 dosing within this experiment exerts an approx. 4.5-fold higher plasma level 8 h after dosing when compared to the identical dosing with the Avacopan*.

*Source: InflaRx data on file. *Avacopan synthesized based on the published structure and publicly available data.*

INF904 Phase I Study: PK Results from SAD Part



Parameter	Unit	*Dose*	INF904	Avacopan*
AUC_{inf}	h.ng/ml	*3 mg*	285	25
		10 mg	1264	130
		30 mg	5956	628
AUC_{last}	h.ng/ml	*3 mg*	254	23
		10 mg	1117	122
		30 mg	5197	557
C_{max}	ng/ml	*3 mg*	21.5	9
		10 mg	74.8	25
		30 mg	289	79
t_{max}	hr	*3 mg*	3.5	1.2
		10 mg	4	1.7
		30 mg	5.01	1.7

Source: Bekker et al. (2016, PLoS One; 11(10): e0164646)
***Please note:** Avacopan data taken from Bekker et al. (2016, PLoS One; 11(10): e0164646) are superimposed in graph for orientation; Avacopan was not included as a comparator in INF904 Phase I study.

In comparison to published data for Avacopan, INF904 is approximately 3-fold higher in C_{max} and 10-fold higher in systemic exposure (AUC_{last}) for comparable doses (3, 10, 30 mg)

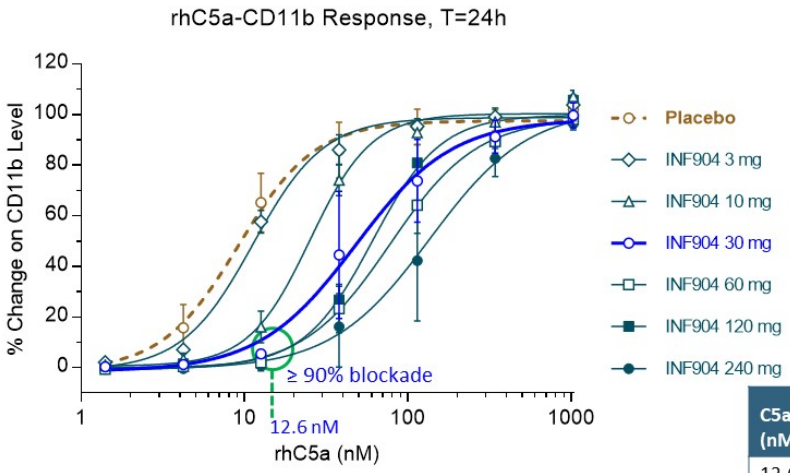
INF904 Phase I Study: Safety Results from SAD Part

Highlights

- INF904 was well tolerated in treated healthy volunteers and resulted in no safety signals of concern in single ascending doses ranging from 3mg to 240mg.
- Overall percentage of adverse events (AEs) in placebo group was higher than in active treated subjects.
- AE severity:
  - Mild: 81
  - Moderate: 9
  - Severe: 0
- No serious AE (SAE) reported at any dosing level.
- 1 moderate AE rated as possibly related to study drug (headache), but subject had received placebo.
- 1 withdrawn subject in cohort 1.4 (60 mg) for unrelated AE.

INF904 Phase I Study: PD Results from SAD Part

*C5a-mediated CD11b upregulation on neutrophils ex vivo at **24h post dosing***



- INF904: In response to 12.64 nM of C5a, ≥ 90% blocking activity was observed in the PD analysis in the dose range of 30-240 mg at the time point of **24-hour** post dosing.
- Avacopan: In response to ~12.64 nM of C5a, approximately 50% blocking activity was observed in the Phase I published data for 30mg dosing at the time point of **12-hour** post dosing. (Bekker et al. PLoS One 2016; 11(10): e0164646)

C5a (nM)	INF904 (Blocking Activity % vs Placebo)					
	3mg	10mg	30mg	60mg	120mg	240mg
12.6	9.6	74.7	**91.5**	**95.7**	**95.2**	**98.7**

INF904 blocking activity for C5a-induced neutrophil activation in human plasma achieved set goal and is clearly differentiated from the published blocking activity of the only marketed comparator

Summary

Topline Results from INF904 Phase I SAD Study

Key Outcomes

- INF904 was well tolerated in treated healthy volunteers and resulted in no safety signals of concern in single ascending doses ranging from 3mg to 240mg.
- INF904 demonstrated a favorable PK profile: Tmax 6 hours, dose proportional exposure from 3 to 240mg.
- INF904 demonstrated a strong C5a blocking potential at C5a concentrations observed in human diseases.
- INF904 can be formulated with a higher drug strength of 30mg per capsule vs. 10mg per capsule for the marketed comparator.

INF904 confirms its best-in-class C5aR inhibitor potential within this Phase I single ascending dose study