

# InflaRx Reports Second Quarter 2021 Financial & Operating Results

- Severe COVID-19 trial enrollment reaches 299 patients; an independent data monitoring committee has recommended to continue the trial as planned after analyzing data from the first 180 evaluable patients
- Type A meeting request submitted to further discuss primary endpoint for the Phase III clinical development of vilobelimab in Hidradenitis Suppurativa
- First three patients dosed with vilobelimab in Phase II Cutaneous Squamous Cell Carcinoma trial
- Dr. Korinna Pilz promoted to Chief Clinical Development Officer
- Cash, cash equivalents and financial assets of approximately €127.5 million as of June 30, 2021

**Jena, Germany, August 5, 2021** – InflaRx (Nasdaq: IFRX), a clinical-stage biopharmaceutical company developing anti-inflammatory therapeutics by targeting the complement system, announced today financial and operating results for the three and six months ended June 30, 2021.

"I am very pleased to announce the promotion of Dr. Korinna Pilz to Chief Clinical Development Officer. Korinna has an impressive background with more than 20 years of drug development experience in biotech and large pharma. Korinna has been instrumental in leading the development of our pipeline programs and building the internal clinical team over the past few years. Our team has been impressed by her professional excellence and we are wishing Korinna a great start in her new role." said Prof. Niels C. Riedemann, Chief Executive Officer and Founder of InflaRx. "Our team has continued to work hard to advance the clinical development of vilobelimab in several indications, including the initiation of our first clinical trial for treating cancer patients. We are pleased that the independent data monitoring committee has recommended that the COVID-19 trial shall continue as planned. Earlier clinical results with vilobelimab in this challenging disease showed promise and suggested that C5a inhibition might be beneficial in critically ill COVID-19 patients. We look forward to the results of the Phase III trial, which is on track to read out by the end of this year. We also expect data readouts from our clinical trials in ANCA-associated Vasculitis and Pyoderma Gangraenosum by year end. With upcoming data from these trials as well as plans to meet



with the FDA to discuss next steps in Hidradenitis Suppurative, it promises to be a busy second half of 2021."

## Recent Corporate Highlights and R&D Update

## Dr. Korinna Pilz promoted to Chief Clinical Development Officer

Dr. Pilz has been promoted effective August 1st, 2021, to the newly created role of Chief Clinical Development Officer. She joined InflaRx in January 2019 as Program Director Oncology and was promoted to Global Head of Clinical Research and Development in November 2019. She has 20 years' experience in NCE and NBE development in several companies, including Boehringer Ingelheim, Roche, Merck KGaA and Bayer, and as a consultant. She has vast experience in early and late-stage clinical development and has helped in gaining marketing authorizations for several products. At InflaRx, she has established and grown the clinical development group and under her leadership the group has initiated several clinical trials, including for vilobelimab in cSCC and COVID-19. Korinna is a licensed Medical Doctor and holds a Diploma in Biology from the University of Düsseldorf. She is a member of ASCO, ESMO, AACR and IASLC.

## Vilobelimab for Hidradenitis Suppurativa (HS)

InflaRx has submitted a Type A meeting request to the U.S. Food and Drug Administration (FDA) for the HS program to discuss the primary endpoint in the Phase III program. InflaRx expects to hold this Type A meeting by the end of Q3.

As previously reported in 2020, InflaRx received scientific advice from the European Medicines Agency (EMA) about the European pathway for regulatory approval, including supporting the use of the International Hidradenitis Suppurativa Severity Score System (IHS4) as the primary endpoint.

Once InflaRx receives final feedback from the FDA on the proposed Phase III primary endpoint, the Company will determine the best path forward for the global development program in HS.

#### Vilobelimab for Severe COVID-19

The Phase III part of the global Phase II/III trial evaluating vilobelimab in mechanically ventilated patients with COVID-19 was initiated in mid-September 2020, and recruitment has reached 299 patients, with 49 sites initiated across several countries, including the United



States, Russia, South Africa and countries in Europe and Latin America. An interim analysis by an independent data monitoring committee (IDMC), which took place in July and analyzed the data of the first 180 patients evaluable for 28-day mortality, led to a recommendation to continue the study as planned. Per recommendations from EMA and FDA, the option to potentially stop the study early on the basis of efficacy was removed from the interim analysis. Additional trial sites are expected to be added, including in the United States. Topline data for all 360 enrolled patients at the 28-day mortality primary endpoint are expected to be available by the end of 2021.

## Vilobelimab for ANCA-associated Vasculitis (AAV)

In the US IXPLORE clinical Phase II study of IFX-1 in AAV, all patients have completed treatment. In May 2021, InflaRx reported topline data for the study, which indicated that vilobelimab, when given in addition to best standard of care, was shown to be well tolerated. Furthermore, InflaRx previously reported that both Part 1 and Part 2 of the AAV Phase II study in Europe (IXCHANGE) are fully enrolled. Data from this randomized, double-blind, placebo-controlled trial with 57 patients are expected by the end of 2021.

## Vilobelimab in Cutaneous Squamous Cell Carcinoma (cSCC)

The Company recently announced that the first patient had been dosed in the open label, multicenter Phase II study evaluating vilobelimab alone and in combination with pembrolizumab in patients with PD-1 or PD-L1 inhibitor resistant/refractory locally advanced or metastatic cSCC.

The study will investigate two independent arms: vilobelimab alone and vilobelimab in combination with pembrolizumab. The main objectives of the trial are to assess antitumor activity and safety of vilobelimab monotherapy and to determine the maximum tolerated or recommended dose, safety and antitumor activity in the combination arm.

So far, a total of three patients have been enrolled in the monotherapy arm. A safety assessment after at least five weeks of treatment will determine continuation of enrollment in the monotherapy and opening of the combination arm.

## Vilobelimab in Pyoderma Gangraenosum

As previously announced, the Phase IIa open label trial has reached the target enrollment goal of 18 patients with moderate to severe PG at sites in the U.S., Canada and Europe.



Promising initial data from the first five patients in the study were announced in 2020. A second interim analysis, including six patients treated at the second dose group until day 99, are expected to be available by the end of Q3 2021. Final results from all patients, including the highest dose group, are expected in the first half of 2022.

## Financial highlights – Q2 2021

Research and development expenses incurred for the six months ended June 30, 2021 increased over the corresponding period in 2020 by €1.6 million to €16.2 million for the six months ended June 30, 2021. This increase was primarily due to the higher expense for the phase III part of our COVID-19 trial and was driven by an overall increase in third-party expenses of €1.0 million. The €0.7 million increase in personnel expenses was mainly related to equity-settled share-based compensation.

General and administrative expenses increased by €0.8 million to €5.7 million for the six months ended June 30, 2021, from €4.9 million for the six months ended June 30, 2020. This increase is attributable to higher expenses from equity-settled share-based compensation recognized in personnel expenses. Furthermore, legal, consulting and other expenses increased by €0.1 million to €2.2 million for the six months ended June 30, 2021, from €2.1 million for the six months ended June 30, 2020.

Net financial result decreased by €0.1 million to €1.0 million for the six months ended June 30, 2021, from €1.1 million for the six months ended June 30, 2020. This decrease is mainly attributable to higher foreign exchange gains, which increased by €2.6 million and higher foreign exchange losses of €2.2 million while interest on marketable securities declined by €0.7 million. Other finance expenses for the six months ended June 30, 2021 include a €43 thousand gain from a reduction in the allowance for expected credit loss on marketable securities.

**Net loss** for the six months ended June 30, 2021 was €20.9 million, compared to €18.3 million for the six month ended June 30, 2020.

On June 30, 2021, the Company's **total funds available** were approximately €127.5 million, composed of cash and cash equivalents (€72.4 million), current and non-current financial assets and other non-current assets (€55.1 million).



Net cash used in operating activities for the six months ended June 30, increased to €18.3 million in the six months ended June 30, 2021, from €18.2 million in the six months ended June 30, 2020.

Additional information regarding these results and other relevant information is included in the notes to the unaudited Condensed Consolidated Financial Statements as of June 30, 2021, as well as the financial statements as of December 31, 2020 in "ITEM 18. Financial statements," which is included in InflaRx's Annual Report on Form 20-F as filed with the U.S. Securities and Exchange Commission (SEC).



# InflaRx N.V. and subsidiaries Unaudited Condensed Consolidated Statements of Operations and Comprehensive Loss for the three and six months ended June 30, 2021 and 2020

	For the three I		For the six months ended June 30,		
(in €, except for share data)	2021 (unaudited)	2020 (unaudited)	2021 (unaudited)	2020 (unaudited)	
Operating Expenses					
Research and development ex-	(44 000 070)	(7.050.000)	(40,000,455)	(4.4.055.405)	
penses General and administrative ex-	(11,299,270)	(7,356,326)	(16,206,155)	(14,655,125)	
	(2,697,839)	(2,326,895)	(5,720,177)	(4,891,698)	
Total Operating Expenses	(13,997,109)	(9,683,221)	(21,926,332)	(19,546,822)	
Other income	15,216	102,332	20,678	197,292	
Other expenses	(279)	(3,450)	(844)	(9,170)	
Operating Result	(13,982,172)	(9,584,339)	(21,906,498)	(19,358,701)	
Finance income	35,622	348,321	58,584	749,756	
Finance expenses	(3,050)	(3,111)	(6,734)	(5,258)	
Foreign exchange result	(826,303)	(593,703)	905,367	547,974	
Other financial result	(5,000)	(200,000)	43,000	(200,000)	
Income Taxes	(0,000)	(200,000)	10,000	(200,000)	
Loss for the Period	(14,780,903)	(10,032,832)	(20,906,280)	(18,266,229)	
LOSS for the remod	(14,700,303)	(10,032,032)	(20,300,200)	(10,200,223)	
Share Information					
Weighted average number of					
shares outstanding	44,186,279	26,172,023	39,024,533	26,138,639	
Loss per share (basic/diluted)	(0.33)	(0.38)	(0.54)	(0.70)	
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Loss for the Period	(14,780,903)	(10,032,832)	(20,906,280)	(18,266,229)	
Other comprehensive income that may be reclassified to profit or loss in subsequent periods:					
Exchange differences on translation of foreign currency	(1,427,302)	(1,452,973)	2,077,397	260,895	
Total Comprehensive Loss	(16,208,205)	(11,485,805))	(18,828,883)	(18,005,334)	



# InflaRx N.V. and subsidiaries Unaudited Condensed Consolidated Statements of Financial Position as of June 30, 2021 and December 31, 2020

in €	June 30,2021 (unaudited)	December 31, 2020
ASSETS		
Non-current assets		
Property and equipment	334,556	408,263
Right-of-use assets	1,592,801	546,694
Intangible assets	291,969	350,183
Other assets	342,899	353,522
Financial assets	272,390	272,268
Total non-current assets	2,834,615	1,930,930
Current assets		
Current other assets	4,140,348	3,734,700
Current tax assets	852,464	1,419,490
Financial assets	54,837,260	55,162,033
Cash and cash equivalents	72,360,428	25,968,681
Total current assets	132,190,500	86,284,904
TOTAL ASSETS	135,025,116	88,215,834
EQUITY AND LIABILITIES Equity		
Issued capital	5,302,354	3,387,410
Share premium	280,261,994	220,289,876
Other capital reserves	28,946,783	26,259,004
Accumulated deficit	(189,251,900)	(168,345,620)
Other components of equity	(1,649,393)	(3,726,791)
Total equity	123,609,838	77,863,880
Non-current liabilities		
Lease liabilities	1,244,785	220,525
Other liabilities	33,990	33,323
Total non-current liabilities	1,278,775	253,847
Current liabilities		
Trade and other payables	8,930,859	8,258,133
Lease liabilities	360,221	338,516
Employee benefits	720,441	1,368,731
Other financial liabilities	124,982	117,727
Provisions		15,000
Total current liabilities	10,136,503	10,098,107
Total Liabilities	11,415,278	10,351,954
TOTAL EQUITY AND LIABILITIES	135,025,116	88,215,834



# InflaRx N.V. and subsidiaries Unaudited Condensed Consolidated Statements of Changes in Shareholders' Equity for the six months ended June 30, 2021 and 2020

(in €, except for share data)	Issued capi- tal	Share premium	Other capital re- serves	Accumulated deficit	Other components of equity	Total equity
(iii c, except for share data)						
Balance as of January 1, 2021	3,387,410	220,289,876	26,259,004	(168,345,620)	(3,726,790)	77,863,880
Loss for the period	_			(20,906,280)		(20,906,280)
Exchange differences on translation of foreign currency	_	_	_	_	2,077,397	2,077,397
Total comprehensive loss	_	_	_	(20,906,280)	2,077,397	(18,828,883)
Issue of ordinary shares	1,873,203	63,269,346	_	_	_	65,142,549
Transaction costs	_	(4,219,222)	_	_	_	(4,219,222)
Equity-settled share-based pay- ment	_	_	2,687,779	_	_	2,687,779
Share options exercised	41,741	921,994	· · · · —	_	_	963,735
Balance as of June 30, 2021	5,302,354	280,261,994	28,946,783	(189,251,900)	(1,649,393)	123,609,838
,						
Balance as of January 1, 2020	3,132,631	211,006,606	25,142,213	(134,362,006)	2,227,228	107,146,673
Loss for the period		_		(18,266,229)	_	(18,266,229)
Exchange differences						
on translation of foreign currency					260,895	260,895
Total comprehensive loss				(18,266,229)	260,895	(18,005,334)
Equity-settled share-based pay-						
ment	_	_	1,484,972	_	_	1,484,972
Share options exercised	19,797	477,149				496,946
Balance as of June 30, 2020	3,152,427	211,483,756	26,627,185	(152,628,234)	2,488,124	91,123,258



# InflaRx N.V. and subsidiaries Unaudited Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2021 and 2020

in€	For the six months ended June 30, 2021 (unaudited)	For the six months ended June 30, 2020 (unaudited)
Operating activities		
Operating activities Loss for the period	(20,906,280)	(18,266,229)
Adjustments for:	(20,900,200)	(10,200,229)
Depreciation & amortization of property and equipment, right-		
of-use assets and intangible assets	337,581	353,976
Net financial result	(1,000,217)	(1,092,472)
Share-based payment expense	2,687,779	1,484,972
Net foreign exchange differences	71,050	(789,528)
Other non-cash adjustments	- 1,000	(. 55,525)
Changes in:		
Other assets	172,001	560,449
Employee benefits	(662,388)	(122,411)
Other liabilities	7,020	341,012
Trade and other payables	672,727	(1,783,200)
Interest received	371,665	1,096,651
Interest paid	(5,491)	(5,455)
Net cash used in operating activities	(18,254,553)	(18,222,235)
Investing activities		
Purchase of intangible assets, property and equipment	(18,734)	(35,107)
Purchase of current financial assets	(27,535,842)	(59,196,096)
Proceeds from the maturity of financial assets	29,497,122	79,504,059
Net cash from investing activities	1,942,546	20,272,857
Financing activities		
Proceeds from issuance of common shares	65,142,549	_
Transaction costs from issuance of common shares	(4,219,222)	_
Proceeds from exercise of share options	963,735	496,946
Repayment of lease liabilities	(183,128)	(183,970)
Net cash from financing activities	61,703,934	312,976
Net increase in cash and cash equivalents	45,391,927	2,363,597
Effect of exchange rate changes on cash and cash equivalents	999,820	903,700
Cash and cash equivalents at beginning of period	25,968,681	33,131,280
Cash and cash equivalents at end of period	72,360,428	36,398,578



## About vilobelimab (IFX-1):

Vilobelimab is a first-in-class monoclonal anti-human complement factor C5a antibody, which highly and effectively blocks the biological activity of C5a and demonstrates high selectivity towards its target in human blood. As a result, vilobelimab leaves the formation of the membrane attack complex (C5b-9) intact as an important defense mechanism, which is not the case for molecules blocking the cleavage of C5. Vilobelimab has been demonstrated to control the inflammatory response driven tissue and organ damage by specifically blocking C5a as a key "amplifier" of this response in pre-clinical studies. Vilobelimab is believed to be the first monoclonal anti-C5a antibody introduced into clinical development. Approximately 300 people have been treated with vilobelimab in clinical trials and the antibody has been shown to be well tolerated. Vilobelimab is currently being developed for various indications, including Hidradenitis Suppurativa, ANCA-associated vasculitis, Pyoderma Gangraenosum as well as COVID-19 pneumonia and Cutaneous Squamous Cell Carcinoma.

## **About InflaRx N.V.:**

InflaRx (Nasdaq: IFRX) is a clinical-stage biopharmaceutical company focused on applying its proprietary anti-C5a technology to discover and develop first-in-class, potent and specific inhibitors of C5a. Complement C5a is a powerful inflammatory mediator involved in the progression of a wide variety of autoimmune and other inflammatory diseases. 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 <a href="https://www.inflarx.com">www.inflarx.com</a>.

#### Contacts:

#### InflaRx N.V.

Jordan Zwick – Chief Strategy Officer

Email: IR@inflarx.de Tel: +1 917-338-6523

## **MC Services AG**

Katja Arnold, Laurie Doyle, Andreas Jungfer

Email: inflarx@mc-services.eu Europe: +49 89-210 2280 US: +1-339-832-0752



#### 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," "believe," "estimate," "predict," "potential" or "continue" and similar expressions. Forwardlooking 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, our ongoing and planned preclinical development and clinical trials; the impact of the COVID-19 pandemic on the Company; the timing and our ability to commence and conduct clinical trials; potential results from current or potential future collaborations; our ability to make regulatory filings, obtain positive guidance from regulators, and obtain and maintain regulatory approvals for our product candidates; our intellectual property position; our ability to develop commercial functions; expectations regarding clinical trial data; our results of operations, cash needs, financial condition, liquidity, prospects, future transactions, growth and strategies; the industry in which we operate; the trends that may affect the industry or us and the risks uncertainties and other factors described under the heading "Risk Factors" in InflaRx's periodic filings with the 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.