



## InflaRx Reports Full Year 2022 Financial and Operating Results

- *Major progress in development of vilobelimab*
  - *Phase III study in PG announced following detailed feedback and recommendations from the U.S. Food and Drug Administration (FDA); clinical trial protocol submitted; first patient expected around mid-2023*
  - *Fast Track and Orphan Drug designations granted for treatment of pyoderma gangrenosum (PG) in the United States and Orphan Drug designation granted in Europe*
  - *Encouraging results from Phase III study in critically ill COVID-19 patients published in The Lancet Respiratory Medicine*
  - *Emergency Use Authorization (EUA) application for treatment of critically ill, invasively mechanically ventilated COVID-19 patients submitted to the FDA; review ongoing*
- *First-in-human clinical trial with oral C5aR inhibitor INF904 initiated in November 2022; first data expected in H2 2023*
- *Amendment of co-development agreement with Staidson and incremental \$2.5 million equity investment by Staidson HK for planned regulatory filing of BDB-001 for COVID-19 in China*
- *Total funds available approximately €83.7 million as of December 31, 2022, funding the company into H2 2025*

**Jena, Germany, March 22, 2023** – InflaRx N.V. (Nasdaq: IFRX), a clinical-stage biopharmaceutical company developing anti-inflammatory therapeutics by targeting the complement system, today announced financial and operating results for the year ended December 31, 2022.

Prof. Niels C. Riedemann, CEO and Founder of InflaRx, commented: “We are very pleased with the exceptional progress we have made in the past year with our lead drug candidate, vilobelimab, in several areas, as well as in advancing our pipeline with a new clinical asset, INF904, an orally available small molecule inhibitor of the C5a receptor. Upon detailed feedback from the FDA related to our development of vilobelimab for the treatment of PG, a rare debilitating and neutrophil driven skin disease, we have designed and submitted a Phase III protocol to the FDA while we are currently initiating the trial. We also submitted an EUA application to treat critically ill, mechanically ventilated patients with COVID-19, who today are



*still facing poor outcomes, and shortly await a decision from the FDA. Further, we expect first results from our ongoing Phase I clinical trial with INF904 and interim results from our Phase II clinical trial in cutaneous squamous cell carcinoma later this year. With these important milestones anticipated, 2023 promises to be an exciting year.”*

## **Recent Highlights and R&D Update**

InflaRx reported on key recent highlights and provided an update on its research and development activities.

### **Vilobelimab in Pyoderma Gangrenosum (PG)**

Final data from an open-label, multi-center Phase IIa exploratory study evaluating the safety and efficacy of vilobelimab in patients with moderate to severe PG were presented in March 2022. The results showed a dose-dependent treatment effect. In the highest dose cohort of 2,400 mg, six out of seven patients demonstrated a clinical remission (Physician Global Assessment (PGA) score  $\leq 1$ ) and closure of the target ulcer.

Based on these compelling results and a productive End-of-Phase II meeting with the FDA in Q3 2022, InflaRx is moving forward with a pivotal Phase III clinical development program in this indication. In January 2023, the Company announced details related to the design of its planned Phase III study, a multi-national, randomized, double-blind, placebo-controlled trial. The Company has submitted the clinical trial protocol to the FDA and plans to begin patient enrollment around mid-2023.

Vilobelimab was granted Orphan Drug designation by both the FDA and the European Medicines Agency (EMA) for the treatment of ulcerative PG in June 2022, and in July was granted Fast Track designation for this indication by the FDA.

### **Vilobelimab for the Treatment of Critically ill COVID-19 Patients**

InflaRx submitted an EUA application to the FDA for vilobelimab for the treatment of critically ill, intubated, mechanically ventilated COVID-19 patients in September 2022. The Company continues to be in active dialogue with and has addressed several requests for information that it received from the FDA. There is no set timeline for a decision from the FDA related to the EUA. The Company will continue to interact closely with the FDA and will provide a timely update when appropriate. If EUA is granted, InflaRx plans to seek full marketing authorization



in major markets, including the United States and Europe and, in parallel, intends to seek partners to support commercialization efforts.

InflaRx also previously received Fast Track designation from the FDA for vilobelimab for the treatment of critically ill, intubated, mechanically ventilated COVID-19 patients.

In September 2022, results from the PANAMO Phase III study, an international, double-blind, placebo-controlled, randomized clinical trial investigating vilobelimab in invasively mechanically ventilated COVID-19 patients, were published in the peer-reviewed journal, *The Lancet Respiratory Medicine*, which included an in-depth statistical analysis supporting the robustness of the observed clinical survival benefit in the study.

Based on current COVID-19 trends, the U.S. Department of Health and Human Services (HHS) expects the COVID-19 federal public health emergency to expire on May 11, 2023. However, HHS has stated that it expects that the FDA will provide continued access to pathways for EUAs for medical products. See <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/faqs-what-happens-euas-when-public-health-emergency-ends>.

In 2021, InflaRx was awarded a grant from the German Ministry of Education and Research and the German Ministry of Health to support the development of vilobelimab for the treatment of COVID-19. As of December 31, 2022, the Company had received €25.6 million in grant funds and still has a maximum amount of €15.9 million available for claiming under the grant throughout the end of the grant term in June 2023.

### **Vilobelimab in Cutaneous Squamous Cell Carcinoma (cSCC)**

InflaRx is conducting an open-label, multicenter Phase II study, evaluating vilobelimab alone and in combination with pembrolizumab in patients with programmed cell death protein-1 (PD-1) or programmed cell death ligand-1 (PD-L1) inhibitor resistant/refractory, locally advanced or metastatic cSCC. Patients are being recruited into two independent arms - vilobelimab as monotherapy (Arm A) and in combination with pembrolizumab (Arm B). The main objectives of the trial are to assess the safety and antitumor activity of vilobelimab monotherapy and to determine the maximum tolerated or recommended dose, safety and antitumor activity in the combination arm in this patient population.

So far, 10 patients have been recruited into Arm A of the study. First data from an interim analysis in patients in Arm A is expected to be available in the first half of 2023. In Arm B of



the study, as of today, 14 patients have been recruited into three dose cohorts (3+6+5). Data from an interim analysis in Arm B are expected to be available in the first half of 2024.

### **C5aR Inhibitor INF904**

In November 2022, the company announced that the first healthy volunteer had been dosed in a randomized, double-blind, placebo-controlled Phase I trial. This single and multiple ascending dose Phase I trial aims to evaluate the safety, tolerability and pharmacokinetics of INF904 in healthy volunteers. The effect of INF904 on C5a-induced downstream activity will also be explored. Results are expected in the second half of 2023. In the future, InflaRx plans to develop INF904 for complement-mediated, chronic autoimmune and inflammatory diseases where oral administration is the preferred choice for patients.

### **Staidson Agreements**

In December 2022, InflaRx amended its existing co-development agreement with Staidson (Beijing) BioPharmaceuticals Co., Ltd. (Staidson) from 2015 to support Staidson in its regulatory approval efforts for its proprietary drug candidate BDB-001 in China. InflaRx will receive royalties of 10% on net sales of BDB-001 for the treatment of COVID-19 in China. InflaRx has granted Staidson an exclusive license for use in China to certain of InflaRx's clinical, manufacturing and regulatory documentation regarding vilobelimab in order to support and facilitate the planned regulatory filing for BDB-001 for the treatment of severely ill COVID-19 patients with the Chinese National Medical Products Administration (NMPA).

In parallel, InflaRx entered into a share purchase agreement with Staidson Hong Kong Investment Company Limited (Staidson HK), an affiliate of Staidson, pursuant to which Staidson HK purchased ordinary shares of InflaRx for an aggregate amount of \$2.5 million at a price of \$5.00 per share. The share purchase agreement also includes an option pursuant to which Staidson HK may in the future purchase, at InflaRx's discretion, additional ordinary shares for an aggregate amount of \$7.5 million.

### **2022 Financial Highlights**

Dr. Thomas Taapken, CFO of InflaRx, said: *"We are well financed to bring vilobelimab to patients, should we receive EUA, as well as to continue our development programs, including initiating a Phase III study in PG later this year. The grant money we have received from the German government for our COVID-19 development work as well as the investment by*



*Staidson further strengthen our financial position, and we have sufficient cash to fund operations into H2 2025.”*

### **Research and Development (R&D) Expenses**

InflaRx's R&D expenses increased by €1.8 million to €37.5 million in 2022, from €35.7 million in 2021. R&D expenses are predominantly comprised of costs for external contract research organizations (CROs) for pre-clinical activities and the conduct of clinical trials, costs for external contract manufacturing organizations (CMOs) for product manufacturing-related activities, costs for professional consultants primarily in the areas of regulatory affairs and intellectual property, as well as personnel expenses.

### **General and Administrative (G&A) Expenses**

InflaRx's G&A expenses increased by €2.9 million to €14.9 million in 2022, from €12.0 million in 2021. The increase is partly attributable to higher consulting and legal costs incurred in enhancing InflaRx's internal control environment as it is complying with the auditor attestation requirement of Section 404(b) of the Sarbanes-Oxley Act of 2002 for the first time due to the loss of its "emerging growth company" status. G&A expenses are predominantly comprised of professional fees for auditors, consulting expenses not related to R&D activities, professional fees for lawyers, cost of facilities, travel, communication and office expenses as well as personnel related expenses.

### **Other Income**

In 2022, InflaRx recognized other income of €20.1 million from grant payments received from the German federal government for the development of vilobelimab in COVID-19, including expenses related to clinical development and manufacturing process development.

### **Net Financial Result**

InflaRx's net financial result increased by €0.7 million to €2.7 million in 2022, from €2.0 million in 2021. This is mainly attributable to a net increase of €0.5 million in foreign exchange income and expense and an increase of €0.5 million in interest income from marketable securities.



### ***Net Loss***

InflaRx incurred a net loss of €29.5 million, or €0.67 per common share, in 2022 compared to €45.6 million, or €1.10 per common share, in 2021.

### ***Liquidity and Capital Resources***

As of December 31, 2022, InflaRx's total funds available amounted to approximately €83.7 million, comprised of €16.3 million of cash and cash equivalents and €67.4 million of marketable securities.

### ***Net Cash Used in Operating Activities***

InflaRx's net cash used in operating activities decreased to €33.7 million in 2022, from €39.9 million in 2021, mainly due to the decrease of loss before income tax resulting mainly from income recognized from the grant received from the German federal government.

### ***Additional Financial Information***

Additional information regarding these results and other relevant information is included in the notes to the financial statements in "Item 18. Financial Statements," which are included in InflaRx's most recent annual report on Form 20-F as filed with the U.S. Securities and Exchange Commission.



**InflaRx N.V. and subsidiaries**  
**Consolidated Statements of Operations and Comprehensive Loss for the Years**  
**Ended December 31, 2022, 2021 and 2020**

in €, except for share information	2022	2021	2020
<b>Operating Expenses</b>			
Research and development expenses	(37,526,090)	(35,697,935)	(25,684,140)
General and administrative expenses	(14,869,564)	(11,984,722)	(8,467,203)
<b>Total Operating Expenses</b>	<b>(52,395,654)</b>	<b>(47,682,657)</b>	<b>(34,151,343)</b>
Other income	20,159,169	54,221	221,748
Other expenses	(1,381)	(6,381)	(13,209)
<b>Operating Result</b>	<b>(32,237,866)</b>	<b>(47,634,817)</b>	<b>(33,942,804)</b>
Finance income	608,679	109,391	887,702
Finance expenses	(45,250)	(24,769)	(26,000)
Foreign exchange result	2,442,298	1,964,135	(776,512)
Other financial result	(252,471)	(44,000)	(126,000)
<b>Income Taxes</b>	<b>—</b>	<b>—</b>	<b>—</b>
<b>Loss for the Period</b>	<b>(29,484,611)</b>	<b>(45,630,059)</b>	<b>(33,983,614)</b>
<b>Share Information</b>			
Weighted average number of shares outstanding	44,207,873	41,629,974	27,064,902
Loss per share (basic/diluted)	(0.67)	(1.10)	(1.26)
<b>Loss for the Period</b>	<b>(29,484,611)</b>	<b>(45,630,059)</b>	<b>(33,983,614)</b>
Other comprehensive income (loss) that may be reclassified to profit or loss in subsequent periods:			
Exchange differences on translation of foreign currency	4,206,810	6,777,061	(5,954,019)
<b>Total Comprehensive Loss</b>	<b>(25,277,801)</b>	<b>(38,852,998)</b>	<b>(39,937,633)</b>



## InflaRx N.V. and subsidiaries

### Consolidated Statements of Financial Position as December 31, 2022 and 2021

in €	2022	2021
<b>ASSETS</b>		
<b>Non-current assets</b>		
Property and equipment	328,920	274,373
Right-of-use assets	1,311,809	1,408,078
Intangible assets	138,905	235,216
Other assets	308,066	336,566
Financial assets	2,900,902	27,206,990
<b>Total non-current assets</b>	<b>4,988,602</b>	<b>29,461,223</b>
<b>Current assets</b>		
Current other assets	14,170,510	10,983,458
Income tax receivable	1,432,087	1,282,177
Financial assets from government grants	732,971	—
Other Financial assets	64,810,135	57,162,266
Cash and cash equivalents	16,265,355	26,249,995
<b>Total current assets</b>	<b>97,411,058</b>	<b>95,677,896</b>
<b>TOTAL ASSETS</b>	<b>102,399,660</b>	<b>125,139,120</b>
<b>EQUITY AND LIABILITIES</b>		
<b>Equity</b>		
Issued capital	5,364,452	5,304,452
Share premium	282,552,633	280,310,744
Other capital reserves	36,635,564	30,591,209
Accumulated deficit	(243,460,290)	(213,975,679)
Other components of equity	7,257,081	3,050,270
<b>Total equity</b>	<b>88,349,440</b>	<b>105,280,996</b>
<b>Non-current liabilities</b>		
Lease liabilities	987,307	1,066,354
Other liabilities	36,877	35,019
<b>Total non-current liabilities</b>	<b>1,024,184</b>	<b>1,101,373</b>
<b>Current liabilities</b>		
Trade and other payables	4,987,538	8,574,244
Liabilities from government grants received	6,209,266	8,300,000
Lease liabilities	369,376	366,171
Employee benefits	1,312,248	1,378,130
Other liabilities	147,608	138,206
<b>Total current liabilities</b>	<b>13,026,036</b>	<b>18,756,751</b>
<b>Total Liabilities</b>	<b>14,050,220</b>	<b>19,858,124</b>
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>102,399,660</b>	<b>125,139,120</b>





**InflaRx N.V. and subsidiaries**  
**Consolidated Statements of Changes in Shareholders' Equity for the Years**  
**Ended December 31, 2022, 2021 and 2020**

in €	Issued capital	Share premium	Other capital re- serves	Accumulated deficit	Other com- ponents of equity	Total equity
<b>Balance as of January 1, 2020</b>	<b>3,132,631</b>	<b>211,006,606</b>	<b>25,142,213</b>	<b>(134,362,006)</b>	<b>2,227,228</b>	<b>107,146,673</b>
Loss for the Period	—	—	—	(33,983,614)	—	(33,983,614)
Exchange differences on translation of foreign currency	—	—	—	—	(5,954,019)	(5,954,019)
<b>Total Comprehensive Loss</b>	<b>—</b>	<b>—</b>	<b>—</b>	<b>(33,983,614)</b>	<b>(5,954,019)</b>	<b>(39,937,633)</b>
Issuance of common shares	234,982	9,535,961	—	—	—	9,770,943
Transaction costs	—	(729,840)	—	—	—	(729,840)
Equity-settled share-based payments	—	—	1,116,791	—	—	1,116,791
Share options exercised	19,797	477,149	—	—	—	496,946
<b>Balance as of December 31, 2020</b>	<b>3,387,410</b>	<b>220,289,876</b>	<b>26,259,004</b>	<b>(168,345,620)</b>	<b>(3,726,791)</b>	<b>77,863,880</b>
Loss for the Period	—	—	—	(45,630,059)	—	(45,630,059)
Exchange differences on translation of foreign currency	—	—	—	—	6,777,061	6,777,061
<b>Total Comprehensive Loss</b>	<b>—</b>	<b>—</b>	<b>—</b>	<b>(45,630,059)</b>	<b>6,777,061</b>	<b>(38,852,998)</b>
Issuance of common shares	1,873,203	63,269,346	—	—	—	65,142,549
Transaction costs	—	(4,219,222)	—	—	—	(4,219,222)
Equity-settled share-based payments	—	—	4,332,205	—	—	4,332,205
Share options exercised	43,839	970,744	—	—	—	1,014,583
<b>Balance as of December 31, 2021</b>	<b>5,304,452</b>	<b>280,310,744</b>	<b>30,591,209</b>	<b>(213,975,679)</b>	<b>3,050,270</b>	<b>105,280,996</b>
Loss for the Period	—	—	—	(29,484,611)	—	(29,484,611)
Exchange differences on translation of foreign currency	—	—	—	—	4,206,810	4,206,810
<b>Total Comprehensive Loss</b>	<b>—</b>	<b>—</b>	<b>—</b>	<b>(29,484,611)</b>	<b>4,206,810</b>	<b>(25,277,801)</b>
Issuance of common shares	60,000	2,289,624	—	—	—	2,349,624
Transaction costs	—	(47,735)	—	—	—	(47,735)
Equity-settled share-based payments	—	—	6,044,356	—	—	6,044,356
<b>Balance as of December 31, 2022</b>	<b>5,364,452</b>	<b>282,552,633</b>	<b>36,635,564</b>	<b>(243,460,290)</b>	<b>7,257,080</b>	<b>88,349,440</b>



## InflaRx N.V. and subsidiaries

### Consolidated Statements of Cash Flows for the Years ended December 31, 2022, 2021 and 2020

in €	2022	2021	2020
<b>Operating activities</b>			
Loss for the Period	(29,484,611)	(45,630,059)	(33,983,614)
Adjustments for:			
Depreciation & amortization of property and equipment, right-of-use assets and intangible assets	596,597	669,434	712,713
Net finance income	(2,753,255)	(2,004,757)	40,810
Share-based payment expense	6,044,356	4,332,205	1,116,791
Net foreign exchange differences	385,359	111,606	(247,322)
Other non-cash adjustments	—	—	3,436
Changes in:			
Financial assets from government grants	(732,971)	—	—
Other assets	(3,308,485)	(7,094,467)	(1,554,611)
Employee benefits	(64,024)	(3,290)	355,545
Other liabilities	9,403	19,863	8,960
Liabilities from government grants received	(2,090,734)	8,300,000	—
Trade and other payables	(3,586,706)	316,112	(4,155,529)
Interest received	1,287,200	1,070,235	1,201,547
Interest paid	(44,946)	(23,633)	(26,387)
<b>Net cash used in operating activities</b>	<b>(33,742,817)</b>	<b>(39,936,751)</b>	<b>(36,527,661)</b>
<b>Investing activities</b>			
Purchase of intangible assets and property and equipment	(162,391)	(37,778)	(94,189)
Purchase of non-current other financial assets	—	—	—
Purchase of current and non-current financial assets	(64,474,543)	(97,516,417)	(101,600,176)
Proceeds from the maturity of current financial assets	83,995,029	71,603,310	123,056,347
<b>Net cash from/ (used in) investing activities</b>	<b>19,358,095</b>	<b>(25,950,885)</b>	<b>21,361,982</b>
<b>Financing activities</b>			
Proceeds from issuance of common shares	2,349,624	65,142,549	9,770,944
Transaction costs from issuance of common shares	(47,735)	(4,219,222)	(729,841)
Proceeds from exercise of share options	—	1,014,583	496,946
Repayment of lease liabilities	(364,430)	(360,644)	(366,156)
<b>Net cash from/ (used in) financing activities</b>	<b>1,937,459</b>	<b>61,577,266</b>	<b>9,171,893</b>
Net increase/(decrease) in cash and cash equivalents	(12,447,262)	(4,310,369)	(5,993,786)
Effect of exchange rate changes on cash and cash equivalents	2,462,622	4,591,683	(1,168,813)
Cash and cash equivalents at beginning of period	26,249,995	25,968,681	33,131,280
<b>Cash and cash equivalents at end of period</b>	<b>16,265,355</b>	<b>26,249,995</b>	<b>25,968,681</b>



### **About Vilobelimab:**

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. Thus, vilobelimab leaves the formation of the membrane attack complex (C5b-9) intact as an important defense mechanism of the innate immune system, which is not the case for molecules blocking C5. In pre-clinical studies, vilobelimab has controlled the inflammatory response driven tissue and organ damage by specifically blocking C5a as a key “amplifier” of this response. Vilobelimab has been shown to be well tolerated within clinical trials in different disease settings. Vilobelimab is being developed for various debilitating or life-threatening inflammatory indications, including pyoderma gangrenosum (PG), severe COVID-19 and cutaneous squamous cell carcinoma (cSCC).

The COVID-19 related work described herein is partly funded by the German Federal Government through grant number 16LW0113 (VILO-COVID). All responsibility for the content of this work lies with InflaRx.

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

InflaRx (Nasdaq: IFRX) is a clinical-stage biopharmaceutical company focused on applying its proprietary anti-C5a and C5aR technologies to discover and develop first-in-class or best-in-class, potent and specific inhibitors of C5a and C5aR. Complement C5a and its receptor C5aR are powerful inflammatory mediators 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 [www.inflarx.de](http://www.inflarx.de).

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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,” “believe,” “estimate,” “predict,” “potential” or “continue” and similar expressions. Forward-looking statements appear in a number of places throughout this release and may include statements regarding the Company’s intentions, beliefs, projections, outlook, analyses and current expectations concerning, among other things, the status of the Company’s EUA application for vilobelimab to treat critical COVID-19 and the FDA’s review of such application; the Company’s ongoing and planned pre-clinical development and clinical trials, including the development of vilobelimab in several indications; the Company’s interactions with regulators regarding the results of clinical trials, clinical trial design and potential regulatory approval pathways; the impact of the COVID-19 pandemic on the Company; the timing and its ability to commence and conduct clinical trials; potential results from current or potential future collaborations; its ability to make regulatory filings, obtain positive guidance from regulators, and obtain and maintain regulatory approvals for its product candidates; its intellectual property position; its ability to develop commercial functions; expectations regarding clinical trial data; decisions regarding the strategic direction of the Company; its results of operations, cash needs, financial condition, liquidity, prospects, future transactions, growth and strategies; the industry in which the Company operates; the trends that may affect the industry or the Company’s business; and the risks, uncertainties and other factors described under the heading “Risk Factors” in Company’s 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 the Company’s 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 the Company assumes no obligation to update these forward-looking statements, even if new information becomes available in the future, except as required by law.