InflaRx Reports Second Quarter 2024 Financial Results and Provides Business Update

- *Hosted research and development (R&D) event focused on the differentiation of INF904 and its potential in addressing significant unmet needs in inflammation & immunology (I&I)*
- *Initiation of a Phase 2a study with INF904 in chronic spontaneous urticaria (CSU) and hidradenitis suppurativa (HS) expected by year-end 2024*
- *First Phase 2a data readout for INF904 expected in the summer of 2025, with Phase 2b trial initiation expected in 2025*
- *Interim analysis for vilobelimab Phase 3 trial in pyoderma gangrenosum (PG) expected in 2025, and by year-end 2024 InflaRx anticipates providing greater precision on this timeline*
- *GOHIBIC (vilobelimab) selected for first* Biomedical Advanced Research and Development Authority (*BARDA)-sponsored clinical trial to evaluate host-directed therapeutics for treating acute respiratory distress syndrome (ARDS)*
- *Cash, cash equivalents and marketable securities of €74.6 million, expected to fund operations into 2026*

Jena, Germany, August 8, 2024 – InflaRx N.V. (Nasdaq: IFRX), a biopharmaceutical company pioneering anti-inflammatory therapeutics targeting the complement system, today announced financial results for the three and six months ended June 30, 2024, and provided an operating update.

Prof. Niels C. Riedemann, Chief Executive Officer and Founder of InflaRx, commented: *"InflaRx continued to advance its differentiated pipeline assets that target significant unmet needs and sizable commercial opportunities in immuno-dermatology. By year-end 2024, we expect to initiate a Phase 2a study with INF904 in chronic spontaneous urticaria and hidradenitis suppurativa, marking an important milestone for us in showcasing INF904's potentially best-in-class clinical profile. InflaRx is also advancing first-in-class vilobelimab in late-stage development for pyoderma gangrenosum, a debilitating condition with no approved therapy in the U.S. or Europe. Furthermore, clinical data presentations and publications during the second quarter, as well as BARDA's inclusion of vilobelimab in a Phase 2 trial for acute respiratory distress syndrome, additionally support the relevance of this antibody, as well as C5a and C5aR more broadly, in treating inflammatory conditions."*

RECENT HIGHLIGHTS AND BUSINESS UPDATE

Oral C5aR inhibitor INF904 – An efficient path in developing a pipeline-in-a-product with Phase 2a trial initiation expected in 2024

In early June the company hosted an R&D event focused on INF904 and its potential in addressing significant unmet needs in I&I. A replay of the event, including the associated agenda and slideshow presentation can be found here.

InflaRx also previously disclosed it will pursue two initial immuno-dermatology indications with INF904 in a single Phase 2a basket trial that is expected to begin by the end of 2024. The trial will be a multi-center, open-label study dosing 75 patients and evaluating multiple INF904 dosing regimens over 4 weeks of treatment in patients with moderate-to-severe CSU and moderate-to-severe HS, with the goal of generating additional safety and pharmacokinetic (PK) data and showing meaningful clinical benefit. InflaRx believes INF904 could address markets with annual revenue potential of $1 billion or more in each indication.

In addition to CSU and HS, InflaRx believes INF904 could address meaningful markets in other immuno-dermatology and in immuno-inflammation indications, including in nephrology, neurology and hematology. While InflaRx intends to focus its resources on its immediate goals addressing CSU and HS, the company continues to assess and monitor the value of pursuing additional areas and applications via potential future collaborations with partners.

INF904 and InflaRx at the 19th European Meeting on Complement in Human Diseases (EMCHD)

InflaRx will present two posters for INF904 featuring new preclinical data at EMCHD 2024, which is being held in Lübeck, Germany, September 2 – 6, 2024. In addition to two poster presentations, InflaRx representatives will participate in a C5a/C5aR-focused panel discussion as well as speak at a satellite symposium.

Vilobelimab in PG – Enrollment ongoing in pivotal Phase 3 trial with interim analysis expected in 2025

InflaRx is conducting a multi-national, randomized, double-blind, placebo-controlled pivotal Phase 3 study of vilobelimab for the treatment of ulcerative PG, a rare, chronic inflammatory form of neutrophilic dermatosis characterized by accumulation of neutrophils in the affected skin areas. The trial has two arms: (1) vilobelimab plus a low dose of corticosteroids tapered over an 8-week period and (2) placebo plus the same dosing of corticosteroids. The primary endpoint of

the study is complete closure of the target ulcer at any time up to 26 weeks after initiation of treatment.

The study, which dosed its first patient in November 2023, has an adaptive design with an interim analysis blinded for the sponsor and investigators planned upon enrollment of approximately 30 patients (15 per arm). Depending on the results of the interim analysis, expected to occur in 2025, the trial sample size will be adapted, or the trial will be terminated due to futility. Given recent encouraging enrollment trends, InflaRx anticipates providing increased precision on the 2025 timing of this interim analysis by year-end 2024. The total enrollment period is projected to be at least two years, depending on the total trial size after sample size adaptation.

Vilobelimab has been granted orphan drug designation for the treatment of PG by both the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA), as well as fast track designation by the FDA.

GOHIBIC (vilobelimab) to be included in BARDA-sponsored Phase 2 ARDS clinical trial

In June 2024, InflaRx announced that GOHIBIC (vilobelimab) had been selected by the BARDA as one of three host-directed investigational therapies to be assessed in a Phase 2 clinical platform study exploring potential new options for the treatment of ARDS. The multicenter, randomized, double-blind, placebo-controlled trial is expected to begin later this year and to be conducted at approximately 60 sites in the U.S., with a total target enrollment of 600 hospitalized adults with ARDS. The primary endpoint will be all-cause mortality at Day 28. This Phase 2 platform study is expected to inform the design of Phase 3 studies and identify a patient subpopulation most likely to benefit from each of the three drug candidates.

GOHIBIC (vilobelimab) combination data presented at ATS 2024

In May 2024, InflaRx announced data presented at the American Thoracic Society (ATS) 2024 International Conference in a poster titled, “Vilobelimab in Combination with Tocilizumab or Baricitinib Dramatically Improves Mortality in Critically Ill COVID-19 Patients”. The data were derived from a post-hoc subgroup analysis of the PANAMO Phase 3 global study, which included a total of 369 patients and was used to support the emergency use authorization (EUA) granted by the FDA in April 2023 for the treatment of critically ill COVID-19 patients. The analysis assessed 28- and 60-day all-cause mortality in the subgroup of patients (n=71) who were treated with the combination of vilobelimab plus tocilizumab or baricitinib versus patients on placebo plus tocilizumab or baricitinib. All patients received standard of care.

The point estimate for 28-day all-cause mortality was 6.3% in the vilobelimab plus tocilizumab or baricitinib arm, and 40.9% in the placebo plus tocilizumab or baricitinib arm: this is a significant relative reduction of 84.6% (HR 0.13; 95% CI:0.03-0.56, p=0.006) between the two arms. Day 60 all-cause mortality was 16.4% and 49.3%, respectively (HR 0.25; 95% CI:0.09-0.68, p=0.006), a significant relative reduction. The co-administration of vilobelimab with baricitinib or tocilizumab was not associated with safety concerns. In addition, demographics of these subgroups were generally well-balanced and comparable to the overall study population.

Dr. Thomas Taapken, Chief Financial Officer of InflaRx, said: *"InflaRx's efficient use of cash and focused development strategy with INF904 and vilobelimab have provided InflaRx a strong cash runway, allowing us to advance major clinical programs toward their next milestones and to fund operations into 2026."*

FINANCIAL HIGHLIGHTS

Revenue

For the six months ended June 30, 2024, the Company realized revenues from product sales of GOHIBIC (vilobelimab) in the amount of €42 thousand. Revenues reported are sales to end customers (hospitals). Sales to distributors do not constitute revenue for the Company under IFRS 15. All revenues are attributed to sales made in the United States.

Cost of sales

Cost of sales during the three and six months ended June 30, 2024 primarily consisted of write-downs of short-lived inventories.

Sales and marketing expenses

Sales and marketing expenses incurred for the six months ended June 30, 2024 increased by €3.0 million compared to the six months ended June 30, 2023. This increase is primarily due to minimal sales and marketing activities incurred during the six months ended June 30, 2023 due to the GOHIBIC EUA approval received in Q2 2023.

R&D expenses

R&D expenses incurred for the six months ended June 30, 2024 decreased by €8.3 million compared to the six months ended June 30, 2023. This decrease is primarily due to higher third-party expenses incurred during the first half of 2023 in connection with our efforts to develop the

commercial manufacturing process and to obtain an EUA for GOHIBIC (vilobelimab). The decrease of third-party expenses is offset by an increase of personnel expenses by €1.2 million. This increase is attributed to higher stock-based compensation expenses.

General and administrative expenses

General and administrative expenses decreased by €0.3 million to €6.8 million for the six months ended June 30, 2024, from €7.1 million for the six months ended June 30, 2023.

Other income

Other income for the six months ended June 30, 2024 amounted to €53 thousand (PY: €12.6 million). There was no income from government grants in 2024 due to the end of the grant period on June 30, 2023.

Net financial result

Net financial result increased by €3.2 million to €4.4 million for the six months ended June 30, 2024, from €1.2 million for the six months ended June 30, 2023. This increase was mainly attributable to a higher foreign exchange result, which increased by €2.9 million.

Net loss

Net loss for the first six months of 2024 amounted to €23.5 million, compared to €19.3 million in the first six months of 2023.

Net cash used in operating activities

Net cash used in operating activities for the first six months of 2024 increased to €27.0 million from €21.7 million for the comparable period in 2023.

Liquidity and capital resources

As of June 30, 2024, InflaRx's total available funds amounted to €74.6 million, composed of €19.2 million in cash and cash equivalents and €55.4 million in marketable securities. These funds are expected to finance operations into 2026.

Additional financial information

Additional information regarding these results and other relevant information is included in the notes to the unaudited interim condensed consolidated financial statements as of June 30, 2024,

as well as the consolidated financial statements as of and for the year ended December 31, 2023, in “ITEM 18. Financial Statements,” in InflaRx’s annual report on Form 20-F for the year ended December 31, 2023, as filed with the U.S. Securities and Exchange Commission (SEC) on March 21, 2024.

InflaRx N.V. and subsidiaries
Unaudited condensed consolidated statements of operations and comprehensive loss for the three and six months ended June 30, 2024 and 2023

	For the three months ended June 30,		For the six months ended June 30	
	2024 (unaudited)	2023 (unaudited)	2024 (unaudited)	2023 (unaudited)
	(in €, except for share data)			
Revenues	6,357	—	42,394	—
Cost of sales	(348,153)	—	(568,674)	—
Gross profit	(341,796)	—	(526,280)	—
Sales and marketing expenses	(1,828,628)	(276,051)	(3,288,167)	(276,051)
Research and development expenses	(10,016,870)	(10,919,595)	(17,318,680)	(25,651,503)
General and administrative expenses	(3,226,098)	(3,540,805)	(6,805,249)	(7,149,359)
Other income	16,730	4,882,908	53,023	12,629,096
Other expenses	—	(2,624)	—	(3,190)
Operating Result	**(15,396,663)**	**(9,856,168)**	**(27,885,353)**	**(20,451,007)**
Finance income	848,243	1,087,011	1,754,148	1,543,047
Finance expenses	(8,732)	(5,052)	(10,844)	(10,580)
Foreign exchange result	711,411	767,646	2,535,787	(369,664)
Other financial result	—	(195,567)	103,285	2,241
Income taxes	**—**	**—**	**—**	**—**
Income (loss) for the period	**(13,845,741)**	**(8,202,130)**	**(23,502,977)**	**(19,285,963)**
Other comprehensive income (loss) that may be reclassified to profit or loss in subsequent periods:				
Exchange differences on translation of foreign currency	28,374	(330)	2,836	(17,116)
Total comprehensive income (Loss)	(13,817,367)	(8,202,460)	(23,500,141)	(19,303,079)
Share information (based on income (loss) for the period)				
Weighted average number of shares outstanding	58,883,272	56,985,734	58,883,272	50,912,459
Income (loss) per share (basic/diluted)	(0.24)	(0.14)	(0.40)	(0.38)

InflaRx N.V. and subsidiaries
Unaudited condensed consolidated statements of financial position
as of June 30, 2024 and December 31, 2023

	June 30, 2024 (unaudited)	December 31, 2023
	(in €)	
ASSETS		
Non-current assets		
Property and equipment	272,446	289,577
Right-of-use assets	950,070	1,071,666
Intangible assets	44,876	68,818
Other assets	230,750	257,267
Financial assets	237,755	9,052,741
Total non-current assets	**1,735,897**	**10,740,069**
Current assets		
Inventories	9,644,241	11,367,807
Current other assets	4,865,751	4,036,650
Trade receivables	23,727	—
Tax receivable	1,775,404	3,791,564
Other financial assets	55,838,699	77,504,518
Cash and cash equivalents	19,152,121	12,767,943
Total current assets	**91,299,943**	**109,468,483**
TOTAL ASSETS	**93,035,840**	**120,208,552**
EQUITY AND LIABILITIES		
Equity		
Issued capital	7,065,993	7,065,993
Share premium	334,211,338	334,211,338
Other capital reserves	43,123,867	40,050,053
Accumulated deficit	(309,630,796)	(286,127,819)
Other components of equity	7,385,002	7,382,166
Total equity	**82,155,403**	**102,581,730**
Non-current liabilities		
Lease liabilities	601,195	745,716
Other liabilities	36,877	36,877
Total non-current liabilities	**638,072**	**782,593**
Current liabilities		
Trade and other payables	8,544,902	11,974,362
Lease liabilities	397,475	374,329
Employee benefits	1,125,663	1,609,766
Other liabilities	174,325	2,885,772
Total current liabilities	**10,242,365**	**16,844,229**
Total liabilities	**10,880,437**	**17,626,822**
TOTAL EQUITY AND LIABILITIES	**93,035,840**	**120,208,552**

InflaRx N.V. and subsidiaries
Unaudited condensed consolidated statements of changes in shareholders' equity for the six months ended June 30, 2024 and 2023

(in €)	Issued capital	Share premium	Other capital reserves	Accumulated deficit	Other components of equity	Total equity
Balance as of January 1, 2024	**7,065,993**	**334,211,338**	**40,050,053**	**(286,127,819)**	**7,382,166**	**102,581,730**
Loss for the period	—	—	—	(23,502,977)	—	(23,502,977)
Exchange differences on translation of foreign currency	—	—	—	—	2,836	2,836
Total comprehensive loss	**—**	**—**	**—**	**(23,502,977)**	**2,836**	**(23,500,141)**
Equity-settled share-based payments	—	—	3,073,813	—	—	3,073,813
Balance as of June 30, 2024	**7,065,993**	**334,211,338**	**43,123,866**	**(309,630,796)**	**7,385,002**	**82,155,403**
Balance as of January 1, 2023	**5,364,452**	**282,552,633**	**36,635,564**	**(243,460,290)**	**7,257,081**	**88,349,440**
Loss for the period	—	—	—	(19,285,963)	—	(19,285,963)
Exchange differences on translation of foreign currency	—	—	—	—	(17,116)	(17,116)
Total comprehensive loss	**—**	**—**	**—**	**(19,285,963)**	**(17,116)**	**(19,303,079)**
Issuance of common shares	1,687,110	54,796,819	—	—	—	56,483,929
Transaction costs	—	(3,360,626)	—	—	—	(3,360,626)
Equity-settled share-based payments	—	—	2,239,397	—	—	2,239,397
Share options exercised	14,431	222,512	**—**	**—**	**—**	236,943
Balance as of June 30, 2023	**7,065,993**	**334,211,338**	**38,874,961**	**(262,746,253)**	**7,239,965**	**124,646,004**

InflaRx N.V. and subsidiaries
Unaudited condensed consolidated statements of cash flows
for the six months ended June 30, 2024 and 2023

	For the six months ended June 30,	
	2024 (unaudited)	**2023 (unaudited)**
	(in €)	
Operating activities		
Loss for the period	(23,502,977)	(19,285,963)
Adjustments for:		
Depreciation & amortization of property and equipment, right-of-use assets and intangible assets	262,932	293,328
Net finance income	(4,382,376)	(1,165,044)
Share-based payment expense	3,073,813	2,239,397
Net foreign exchange differences	(101,055)	(23,953)
Changes in:		
Financial assets from government grants	—	(4,460,274)
Inventories	1,723,566	(578,705)
Trade receivables	(23,727)	—
Other assets	1,213,575	6,295,975
Employee benefits	(484,102)	(411,774)
Other liabilities	(2,711,447)	60,443
Liabilities from government grants received	—	(5,407,634)
Trade and other payables	(3,429,460)	213,270
Interest received	1,369,670	556,068
Interest paid	(11,048)	(10,777)
Net cash used in operating activities	**(27,002,634)**	**(21,685,642)**
Investing activities		
Purchase of intangible assets, property and equipment	(28,310)	(24,673)
Purchase of current financial assets	(23,254,210)	(83,071,163)
Proceeds from the maturity of financial assets	56,221,278	55,202,491
Net cash from/(used in) investing activities	**32,938,758**	**(27,893,346)**
Financing activities		
Proceeds from issuance of common shares	—	56,483,929
Transaction costs from issuance of common shares	—	(3,360,626)
Proceeds from exercise of share options	—	236,943
Repayment of lease liabilities	(193,053)	(184,791)
Net cash from/(used in) financing activities	**(193,053)**	**53,175,455**
Net increase/(decrease) in cash and cash equivalents	5,743,071	3,596,467
Effect of exchange rate changes on cash and cash equivalents	641,107	(345,862)
Cash and cash equivalents at beginning of period	12,767,943	16,265,355
Cash and cash equivalents at end of period	**19,152,121**	**19,515,959**

About GOHIBIC (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 been shown to control the inflammatory response-driven tissue and organ damage by specifically blocking C5a as a key “amplifier” of this response. In addition to development in COVID-19, vilobelimab is also being developed for various debilitating or life-threatening inflammatory indications, including PG.

In April 2023, the FDA issued the EUA for GOHIBIC (vilobelimab) for the treatment of COVID-19 in hospitalized adults when initiated within 48 hours of receiving invasive mechanical ventilation (IMV) or extracorporeal membrane oxygenation (ECMO). In January 2024, InflaRx announced the launch of The InflaRx Commitment Program, pursuant to which the cost of GOHIBIC (vilobelimab) will be refunded for up to six (6) administered inpatient doses (the full treatment course) to institutions that meet the eligibility requirements, for patients who were administered GOHIBIC (vilobelimab) in line with its EUA and who died due to COVID-19 in the intensive care unit.

The Marketing Authorization Application (MAA) for the treatment of adult patients with SARS-CoV-2 induced septic ARDS receiving IMV or ECMO is under regulatory review by the European Committee for Medicinal Products for Human Use under the centralized procedure, which applies to all 27 member states of the European Union.

About INF904

INF904 is an orally administered, small molecule inhibitor of the C5a receptor that has shown 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. PK / 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.

About InflaRx

InflaRx (Nasdaq: IFRX) is a biopharmaceutical 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 is also developing INF904, an orally administered, small molecule inhibitor of the C5a receptor. 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.

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

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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, current expectations and the risks, uncertainties and other factors described under the heading "Risk factors" and "Cautionary statement regarding forward looking statements" in our periodic filings with the SEC. 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.