Annexon Highlights Recent Pipeline and Business Progress and Reports Second Quarter 2023 Financial Results

August 7, 2023

ARCHER Trial Results Presented at ASRS Further Demonstrate Preservation of Visual Function in Patients with Geographic Atrophy; Company to Engage Regulatory Agencies to Determine Optimal Path Forward

Multiple Key Catalysts Expected in Second Half 2023, Including Completion of Enrollment in the Phase 3 Pivotal Trial of ANX005 in GBS and Phase 1 Data from ANX1502 Oral Small Molecule

Company to Provide Updates Across its Portfolio of Complement Therapies During R&D Day in Second Half 2023

Strong Financial Position with Operating Runway into 2025

BRISBANE, Calif., Aug. 07, 2023 (GLOBE NEWSWIRE) -- Annexon, Inc. (Nasdaq: ANNX), a clinical-stage biopharmaceutical company developing a new class of complement medicines for patients with classical complement-mediated autoimmune, neurodegenerative and ophthalmic disorders, today highlighted recent progress across its business and portfolio of complement therapies and reported second quarter 2023 financial results.

"This quarter, we made meaningful progress across our clinical-stage portfolio of medicines, which are squarely focused on stopping classical complement's aggressive inflammatory cascade where it starts on diseased tissue to provide the most complete protection against this harmful inflammation and its resulting damage," said Douglas Love, president and CEO of Annexon. "Following our recent ARCHER data, we now have clinical proof-of-concept in three difficult-to-treat diseases: Guillain-Barré Syndrome (GBS), Huntington's disease and geographic atrophy (GA). Together, these data demonstrate the differentiated mechanism of inhibiting C1q to provide functional benefits for patients living with complement-mediated diseases. As we look ahead, we remain focused on executing toward important near-term milestones, including for our pivotal GBS program and oral small molecule program, in the second half of 2023. We look forward to providing additional updates on our progress and plans at our R&D Day later this year."

Recent Corporate and Pipeline Updates

- **Totality of Data from ARCHER Phase 2 Trial Highlights Potential of ANX007 as a Differentiated Treatment for GA; Company to Engage with Regulators on Path Forward:** Annexon presented data from the ongoing ARCHER Phase 2 trial in patients with GA. Initial data reported in May 2023 show that treatment with ANX007 resulted in a statistically significant, dose-dependent preservation of visual function in patients with GA. Subsequently, the company presented additional analyses evaluating the effect of ANX007 treatment on best corrected visual acuity (BCVA) and the mean rate of change (slope) in GA lesion area during an oral presentation at the American Society of Retina Specialists (ASRS) 2023 Annual Meeting, which underscored ANX007's potential as the first complement therapy to preserve visual acuity in GA. Based on the totality of data from the ARCHER Phase 2 trial, Annexon plans to engage with U.S. and EU regulatory agencies to determine the optimal path forward for ANX007.
- **Strengthened Leadership Team with Appointment of Chief Medical Officer:** Annexon recently announced the appointment of Jamie Dananberg, M.D., as chief medical officer. Dr. Dananberg joins Annexon with more than 20 years of drug development experience across a variety of therapeutic areas in the pharmaceutical and biotechnology industries.

Key 2023-2024 Anticipated Milestones

Corporate

- Annexon plans to provide pipeline updates and outline key milestones across its business and portfolio of complement-targeted therapies during an R&D Day in the second half of 2023. Details for the event will be announced at a future date.

Flagship Programs

- **ANX005 in GBS:** Enrollment in the Phase 3 pivotal trial of ANX005 in patients with GBS is progressing and expected to be completed in the second half of 2023, with initial topline clinical results anticipated during the first half of 2024.
- **ANX1502 in autoimmune diseases:** Enrollment is underway in the multiple-ascending dose Phase 1a trial in healthy volunteers, with data expected to be reported in the second half of 2023.
- **ANX005 in HD:** A planned Phase 3 trial in HD is now expected to be initiated in 2024 as the company prioritizes near-term pivotal development activities for GA.

Next Wave Programs

- **ANX009 in LN:** Initial clinical data from the Phase 1b signal-finding trial of ANX009 for LN is expected in the second half

of 2023.

- **ANX005 in ALS:** Enrollment continues in the Phase 2a trial. Following encouraging preliminary results which showed slowing of disease progression, additional data are expected in the second half of 2023.

Second Quarter 2023 Financial Results

- **Cash and operating runway:** Cash and cash equivalents and short-term investments were $192.9 million as of June 30, 2023. Based on the current operating plan, Annexon continues to expect its cash, cash equivalents and marketable securities as of June 30, 2023, to be sufficient to fund the company's planned operating expenses into 2025.
- **Research and development (R&D) expenses:** R&D expenses were $30.3 million for the quarter ended June 30, 2023, reflecting the advancement of the company's late-stage flagship programs, including GBS and GA, compared to $29.1 million for the quarter ended June 30, 2022.
- **General and administrative (G&A) expenses:** G&A expenses were $7.4 million for the quarter ended June 30, 2023, compared to $8.3 million for the quarter ended June 30, 2022.
- **Net loss:** Net loss was $35.2 million or $0.47 per share for the quarter ended June 30, 2023, compared to $37.1 million or $0.96 per share for the quarter ended June 30, 2022.

About Annexon

Annexon (Nasdaq: ANNX) is a clinical-stage biopharmaceutical company seeking to bring game-changing medicines to patients with classical complement-mediated diseases of the body, brain and eye. The classical complement pathway within the immune system, when overactivated, drives inflammation in a host of autoimmune, neurodegenerative and ophthalmic diseases. Annexon is advancing a new class of complement medicines targeting the early classical cascade and all downstream pathway components that contribute to disease, while selectively preserving the beneficial immune functions of the other complement pathways. Annexon is rigorously developing a pipeline of diversified product candidates across multiple mid- to late-stage clinical trials, with clinical data anticipated throughout 2023 and beyond.

Forward Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. In some cases, you can identify forward-looking statements by terminology such as "aim," "anticipate," "assume," "believe," "contemplate," "continue," "could," "design," "due," "estimate," "expect," "goal," "intend," "may," "objective," "plan," "positioned," "potential," "predict," "seek," "should," "suggest," "target," "on track," "will," "would" and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology. All statements other than statements of historical facts contained in this press release are forward-looking statements. These forward-looking statements include, but are not limited to, statements about: anticipated milestones; plans to engage with U.S. and EU regulatory agencies to determine the optimal path forward for ANX007; cash operating runway; the potential benefits from treatment with anti-C1q therapy; timing of data reports; and continuing advancement of the company's portfolio. Forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that could cause actual results and events to differ materially from those anticipated, including, but not limited to, risks and uncertainties related to: the company's history of net operating losses; the company's ability to obtain necessary capital to fund its clinical programs; the early stages of clinical development of the company's product candidates; the effects of public health crises on the company's clinical programs and business operations; the company's ability to obtain regulatory approval of and successfully commercialize its product candidates; any undesirable side effects or other properties of the company's product candidates; the company's reliance on third-party suppliers and manufacturers; the outcomes of any future collaboration agreements; and the company's ability to adequately maintain intellectual property rights for its product candidates. These and other risks are described in greater detail under the section titled "Risk Factors" contained in the company's Annual Report on Form 10-K and Quarterly Reports on Form 10-Q and the company's other filings with the SEC. Any forward-looking statements that the company makes in this press release are made pursuant to the Private Securities Litigation Reform Act of 1995, as amended, and speak only as of the date of this press release. Except as required by law, the company undertakes no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise.

Investor Contact:

Chelcie Lister
THRUST Strategic Communications
chelcie@thrustsc.com

Media Contact:

Sheryl Seapy
Real Chemistry
949-903-4750
sseapy@realchemistry.com

ANNEXON, INC.
Condensed Consolidated Statements of Operations
(in thousands, except share and per share amounts)
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development (1)	$ 30,251	$ 29,106	$ 62,596	$ 56,104
General and administrative (1)	7,440	8,303	16,337	16,731
Total operating expenses	37,691	37,409	78,933	72,835
Loss from operations	(37,691)	(37,409)	(78,933)	(72,835)
Interest and other income, net	2,503	272	5,069	325
Net loss	$ (35,188)	$ (37,137)	$ (73,864)	$ (72,510)
Net loss per share, basic and diluted	$ (0.47)	$ (0.96)	$ (0.99)	$ (1.88)
Weighted-average shares used in computing net loss per share, basic and diluted	75,230,003	38,584,400	74,546,995	38,573,950

(1) Includes the following stock-based compensation expense:

Research and development	$ 2,307	$ 2,117	$ 4,558	$ 4,076
General and administrative	$ 2,353	$ 2,403	$ 4,709	$ 4,696

ANNEXON, INC.
Condensed Consolidated Balance Sheets
(in thousands)

	June 30, 2023	December 31, 2022
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 113,614	$ 140,020
Short-term investments	79,324	102,637
Prepaid expenses and other current assets	4,623	5,441
Total current assets	197,561	248,098
Restricted cash	1,032	1,032
Property and equipment, net	15,830	16,838
Operating lease right-of-use assets	18,590	19,128
Total assets	$ 233,013	$ 285,096
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 7,161	$ 7,416
Accrued liabilities	8,953	13,448
Operating lease liabilities, current	1,616	1,316
Other current liabilities	161	180
Total current liabilities	17,891	22,360
Operating lease liabilities, non-current	30,398	31,542
Total liabilities	48,289	53,902
Stockholders' equity:		
Common stock	53	48
Additional paid-in capital	696,968	669,780
Accumulated other comprehensive loss	(171)	(372)
Accumulated deficit	(512,126)	(438,262)
Total stockholders' equity	184,724	231,194
Total liabilities and stockholders' equity	$ 233,013	$ 285,096