Annexon Biosciences Highlights Business and Portfolio Progress and Key Anticipated Milestones and Reports Second Quarter 2022 Financial Results

August 8, 2022

Advancing Robust Pipeline of Five Clinical-Stage Product Candidates Following ANX105 and ANX1502 Phase 1 Trial Initiations

Multiple Clinical Readouts Anticipated throughout 2022 and 2023

Operating Runway into the Second Half of 2025 Following $130 Million Private Placement

BRISBANE, Calif., Aug. 08, 2022 (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 outlined progress across its broad pipeline of fit-for-purpose product candidates and anticipated clinical milestones, and reported second quarter 2022 financial results.

"Annexon was founded with an ambitious goal: deliver game-changing treatments to patients suffering from complement-mediated diseases by stopping the classical complement cascade *at its start.* I'm encouraged by the progress made in the first half of this year toward turning our vision into a reality," said Douglas Love, Esq., president and chief executive officer of Annexon. "We're rigorously advancing our pipeline of five clinical-stage drug candidates, each with a substantial and unique value proposition across autoimmune, ophthalmic and neurodegenerative indications. We are planning for initial clinical data on ANX005 and ANX009 in multiple autoimmune diseases later this year, made important regulatory progress in our ophthalmic program with the granting of Fast Track Designation to ANX007 for the treatment of geographic atrophy, and initiated clinical dosing with ANX1502, an oral small molecule complement agent, as well as with ANX105, a next-generation monoclonal antibody. With the proceeds from our recent financing, we are well-positioned to execute our milestones with a multi-year runway into the second half of 2025. Overall, we're invigorated by the promise of our platform and pipeline to make a meaningful difference in the treatment landscape for patients."

Portfolio Highlights

- **Phase 1 Clinical Trial Initiated for ANX1502, a Potential First-in-Class, Oral Small Molecule:** Annexon has initiated dosing in its Phase 1 clinical trial of ANX1502, a potential first-in-class, investigational oral small molecule inhibitor of the classical complement cascade designed for the treatment of a range of autoimmune diseases. The Phase 1 trial is a randomized, double-blind, placebo-controlled study designed to evaluate the safety, tolerability, pharmacokinetics (PK), and pharmacodynamics (PD) of single and multiple ascending doses of orally administered ANX1502. Annexon is actively enrolling healthy participants in the single-ascending dose (SAD) portion of the trial.

- **Phase 1 Clinical Trial Initiated for ANX105, a Next-generation Monoclonal Antibody:** Annexon recently initiated dosing in its first-in-human clinical trial of ANX105, an investigational next-generation monoclonal antibody (mAb) with enhanced dosing properties designed to treat chronic autoimmune and neurodegenerative diseases. The Phase 1 trial is a randomized, double-blind, placebo-controlled study designed to evaluate the safety, tolerability, PK and PD of single and multiple ascending doses of ANX105 administered intravenously. Annexon is actively enrolling healthy participants in the SAD portion of the trial.

- **Fast Track Designation Granted by FDA for ANX007 for GA:** The U.S. Food and Drug Administration (FDA) granted Fast Track designation to ANX007, an investigational antibody antigen-binding-fragment (Fab), for the treatment of geographic atrophy (GA). GA is the leading cause of blindness resulting from damaged and dying retinal cells. ANX007 is formulated for intravitreal administration and designed to inhibit C1q *locally in the eye*. The company completed enrollment in its global Phase 2 clinical trial of ANX007 in patients with GA, and patient treatment is ongoing.

- **Final Data from Phase 2 Clinical Trial of ANX005 Demonstrated Upstream Classical Complement Inhibition Associated with Clinical Benefit in Huntington's Disease:** Annexon reported final data from its Phase 2 clinical trial of ANX005 in patients with Huntington's disease (HD). The data showed that ANX005 demonstrated full C1q target inhibition and was generally well-tolerated. Additionally, disease progression was stabilized in the overall patient population through the nine-month study and the rapid improvement in clinical outcome measures was maintained in patients with high baseline complement activity through the entire nine-month study. Based on these data, Annexon plans to engage with regulatory authorities in the second half of 2022 to assess the opportunity for a well-controlled trial in HD leveraging a precision medicine approach.

Business Highlights

- **Operating Runway Extended into the Second Half of 2025:** In July 2022, Annexon closed a private placement, resulting in gross proceeds of approximately $130 million, before deducting placement agent fees and other expenses. The

proceeds from the private placement, combined with the company's current cash, cash equivalents and marketable securities, are expected to be sufficient to fund the company's current operating plan into the second half of 2025, which is expected to include data readouts across clinical trials for each ANX005, ANX007, ANX009, ANX1502 and ANX105 in a range of complement-mediated diseases.

Key Anticipated Milestones

Annexon is rigorously advancing five clinical-stage drug candidates, each with distinct routes of administration, anticipated dosing schedules, and a fit-for-purpose design to selectively inhibit the classical complement pathway in specific compartments of the body, brain or eye. The company anticipates several potential catalysts across its pipeline throughout 2022 and 2023.

ANX005: intravenously administered mAb

- Initial data from its ongoing Phase 2 trial in patients with wAIHA in the second half of 2022
- Data from its ongoing Phase 2/3 trial in patients with GBS in 2023
- Data from its ongoing Phase 2 trial in patients with ALS in 2023

ANX007: intravitreally administered Fab

- Initial data from its ongoing Phase 2 trial in patients with GA in the first half of 2023, with additional data after the conclusion of the six-month off-treatment period in the second half of 2023

ANX009: subcutaneously administered Fab

- Initial data from its Phase 1b trial in patients with lupus nephritis in the second half of 2022, with full data in 2023

ANX1502: orally administered small molecule

- First-in-human data from its ongoing Phase 1 trial of ANX1502 in 2023

ANX105: intravenously administered mAb

- First-in-human data from its ongoing Phase 1 trial of ANX105 in 2023

Second Quarter 2022 Financial Results

- **Cash and operating runway:** Cash and cash equivalents and short-term investments were $177.6 million as of June 30, 2022, which does not include the approximately $130 million in gross proceeds from the company's recently completed private placement. Annexon believes that its current cash, cash equivalents and marketable securities, combined with the proceeds from the private placement, will be sufficient to fund the company's current operating plan into the second half of 2025.
- **Research and development (R&D) expenses:** R&D expenses were $29.1 million for the quarter ended June 30, 2022, compared to $24.6 million for the quarter ended June 30, 2021.
- **General and administrative (G&A) expenses:** G&A expenses were $8.3 million for the quarter ended June 30, 2022, compared to $6.8 million for the quarter ended June 30, 2021.
- **Net loss:** Net loss was $37.1 million or $0.96 per share for the quarter ended June 30, 2022, compared to $31.3 million or $0.82 per share for the quarter ended June 30, 2021.

About Annexon

Annexon (Nasdaq: ANNX) is a clinical-stage biopharmaceutical company that aims to bring game-changing medicines to patients with classical complement-mediated diseases of the body, brain and eye. The classical complement cascade is a seminal pathway within the immune system that anchors and drives 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 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 2022 and 2023. For more information, visit www.annexonbio.com.

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; cash operating runway; the potential benefits from treatment with anti-C1q therapy; timing of data reports and trial initiation and design; and continuing advancement of the company's innovative 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 COVID-19 or other 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.

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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,	
	2022	2021	2022	2021
Operating expenses:				
Research and development (1)	$ 29,106	$ 24,572	$ 56,104	$ 45,268
General and administrative (1)	8,303	6,801	16,731	12,307
Total operating expenses	37,409	31,373	72,835	57,575
Loss from operations	(37,409)	(31,373)	(72,835)	(57,575)
Interest and other income (expense), net	272	79	325	221
Net loss	(37,137)	(31,294)	(72,510)	(57,354)
Net loss attributable to common stockholders	$ (37,137)	$ (31,294)	$ (72,510)	$ (57,354)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.96)	$ (0.82)	$ (1.88)	$ (1.50)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	38,584,400	38,277,950	38,573,950	38,219,143
(1) Includes the following stock-based compensation expense:				
Research and development	$ 2,117	$ 2,402	$ 4,076	$ 3,948
General and administrative	$ 2,403	$ 2,115	$ 4,696	$ 3,531

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

	June 30, 2022 (Unaudited)	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 104,614	$ 74,843
Short-term investments	72,980	167,872
Prepaid expenses and other current assets	3,778	4,978
Total current assets	181,372	247,693
Restricted cash	1,032	1,166

Property and equipment, net	17,418	17,848
Operating lease right-of-use assets	19,864	20,333
Other non-current assets	1,018	—
Total assets	$ 220,704	$ 287,040
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 10,301	$ 11,153
Accrued liabilities	8,060	9,250
Operating lease liabilities, current	1,729	1,202
Other current liabilities	164	139
Total current liabilities	20,254	21,744
Operating lease liabilities, non-current	32,406	33,387
Total liabilities	52,660	55,131
Stockholders' equity:		
Common stock	39	39
Additional paid-in capital	537,269	528,365
Accumulated other comprehensive loss	(439)	(180)
Accumulated deficit	(368,825)	(296,315)
Total stockholders' equity	168,044	231,909
Total liabilities and stockholders' equity	$ 220,704	$ 287,040