Annexon Reports Third Quarter 2022 Financial Results and Plans to Provide Updates on Complement Therapeutic Portfolio in January 2023

November 3, 2022

Company to provide portfolio updates across autoimmune, neurodegeneration and ophthalmology therapeutic franchises in early January

Presentations at upcoming scientific conferences highlight company's novel approach to treating complement-mediated diseases of the body, brain and eye

Company well-funded with operating runway into the second half of 2025

BRISBANE, Calif., Nov. 03, 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 reported third quarter 2022 financial results. Additionally, Annexon announced plans to provide updates and outline anticipated milestones across its business and portfolio of complement-targeted therapies in January 2023.

"2022 has been a year of marked progress. With compelling clinical and biomarker data from ANX005 in both Guillain-Barré Syndrome (GBS) and Huntington's disease (HD), we are enthusiastic about its future as we advance a late-stage GBS trial and prepare to initiate a late-stage HD trial. Further, we are on-track to evaluate data in December from multiple signal-finding studies in our autoimmune franchise, as well as safety and target engagement data with our first-in-class oral, small molecule, ANX1502, which is progressing well through Phase 1 dose-escalation," said Douglas Love, president and chief executive officer of Annexon. "We are also excited about ANX007, which has demonstrated target engagement and tissue penetration preclinically and in patients. Our optimally designed Phase 2 ARCHER trial of ANX007 for geographic atrophy (GA) is underway, which enrolled patients with baseline characteristics consistent with those who have benefited from other complement therapies. Distinct from those agents, ANX007 is uniquely designed to block both upstream and downstream complement activity, and we look forward to reviewing data from the ARCHER trial in the first half of 2023."

Love continued, "We remain sharply focused on building on our insights and execution through the remainder of this year and in the year ahead. This is an exciting time for Annexon as we execute a purposeful strategy to efficiently evaluate a wide array of diseases for which the classical pathway drives disease burden. With the most comprehensive classical complement pipeline in development, we're rigorously pursuing multiple paths to drive value across our portfolio for patients, employees and our supporters."

Upcoming Medical Meeting Presentations

- **The Retina Society 55th Annual Scientific Meeting:** Annexon will present preclinical data on ANX007 as a potential treatment for GA during an oral session at the 2022 Retina Society Annual Meeting. ANX007 is a novel antibody antigen-binding-fragment formulated for intravitreal administration and has demonstrated full inhibition of C1q locally in the eye of glaucoma patients. Annexon is currently evaluating ANX007 in patients with GA in its Phase 2 ARCHER trial. Initial data from the ARCHER trial are anticipated in the first half of 2023, with full data after the conclusion of the six-month off-treatment period in the second half of 2023.

  Title: Inhibition of C1q protects photoreceptor synapses in a light damage model and is a potential treatment for geographic atrophy
  Session: Age-Related Macular Degeneration I
  Date/Time: Thursday, Nov. 3, 2022, 7:43 a.m. PT

- **Huntington's Study Group (HSG) 2022 Annual Meeting:** Annexon will present a review of new biomarker data as well as previously reported clinical results from its Phase 2 clinical trial of ANX005 in HD during both an oral and poster session at HSG 2022. The Phase 2 trial was completed in mid-2022, and study results showed that ANX005 was generally well-tolerated, led to robust and sustained C1q inhibition, and demonstrated improved clinical outcomes through the nine-month study that included disease stabilization in all patients and rapid clinical benefit in the subgroup of patients with high baseline complement activity.

  New biomarker data from the trial to be reported at HSG suggest that ANX005 also had a positive impact on neuroinflammation. A rapid and sustained reduction in downstream complement activation and neuroinflammation, as measured by CSF C3a and C3 levels, respectively, was observed through the nine-month study. In addition, a trend of decreased CSF YKL40, a glycoprotein produced by inflammatory and other stressed cells, suggested a positive impact of ANX005 on microglial activity and neuroinflammation in patients who exhibited an improved clinical response. In aggregate, the Phase 2 data support the continued advancement of ANX005 for the treatment of HD, and the company plans to engage with regulators on next steps for the program by year-end.

  Oral Session Title: Results from a Phase 2 Study of ANX005 in Patients with Manifest Huntington's Disease and Current

Thinking on Upcoming Global Phase 2/3 Study Design
Session: Clinical Trial Round-Up Part 2
Date/Time: Thursday, Nov. 3, 2022, 5:00-6:00 p.m. ET

Poster Session Title: A Phase 2 Open-Label Study to Assess the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of Intravenous ANX005 in Patients with, or at Risk of, Manifest Huntington's Disease (HD)
Session: HSG Expo
Date/Time: Thursday, Nov. 3, 2022, 6:00-8:00 p.m. ET

Third Quarter 2022 Financial Results

- **Cash and operating runway:** Cash and cash equivalents and short-term investments were $269.5 million as of September 30, 2022. Annexon continues to believe that its current cash, cash equivalents and marketable securities 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 $27.9 million for the quarter ended September 30, 2022, compared to $27.6 million for the quarter ended September 30, 2021.
- **General and administrative (G&A) expenses:** G&A expenses were $8.2 million for the quarter ended September 30, 2022, compared to $8.1 million for the quarter ended September 30, 2021.
- **Net loss:** Net loss was $35.1 million or $0.51 per share for the quarter ended September 30, 2022, compared to $35.6 million or $0.93 per share for the quarter ended September 30, 2021.

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 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 readouts 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; cash operating runway; engagement with regulators; upcoming medical meeting presentations; the potential benefits from treatment with anti-C1q therapy; timing of data reports; and continuing advancement of the company's innovative portfolio and progression of clinical studies. 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.

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 September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development (1)	$ 27,862	$ 27,581	$ 83,966	$ 72,849
General and administrative (1)	8,207	8,099	24,938	20,406
Total operating expenses	36,069	35,680	108,904	93,255
Loss from operations	(36,069)	(35,680)	(108,904)	(93,255)
Interest and other income (expense), net	1,015	82	1,340	303
Net loss	(35,054)	(35,598)	(107,564)	(92,952)
Net loss attributable to common stockholders	$ (35,054)	$ (35,598)	$ (107,564)	$ (92,952)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.51)	$ (0.93)	$ (2.21)	$ (2.43)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	68,652,859	38,341,110	48,710,433	38,261,359
(1) Includes the following stock-based compensation expense:				
Research and development	$ 2,433	$ 2,382	$ 6,509	$ 6,330
General and administrative	$ 2,478	$ 2,046	$ 7,174	$ 5,577

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

	September 30, 2022 (Unaudited)	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 210,658	$ 74,843
Short-term investments	58,861	167,872
Prepaid expenses and other current assets	5,258	4,978
Total current assets	274,777	247,693
Restricted cash	1,032	1,166
Property and equipment, net	17,093	17,848
Operating lease right-of-use assets	19,616	20,333
Other non-current assets	204	—
Total assets	$ 312,722	$ 287,040
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 6,921	$ 11,153
Accrued liabilities	11,323	9,250
Operating lease liabilities, current	1,806	1,202
Other current liabilities	170	139
Total current liabilities	20,220	21,744
Operating lease liabilities, non-current	31,900	33,387
Total liabilities	52,120	55,131
Stockholders' equity:		
Common stock	48	39
Additional paid-in capital	664,839	528,365
Accumulated other comprehensive loss	(406)	(180)
Accumulated deficit	(403,879)	(296,315)
Total stockholders' equity	260,602	231,909

Total liabilities and stockholders' equity	$ 312,722	$ 287,040