Annexon Biosciences Reports Fourth Quarter and Full-Year 2020 Financial Results with Recent Business Highlights

March 25, 2021

SOUTH SAN FRANCISCO, Calif., March 25, 2021 (GLOBE NEWSWIRE) -- Today Annexon, Inc. (“Annexon”) (Nasdaq: ANNX), a clinical-stage biopharmaceutical company developing a pipeline of novel therapies for patients with classical complement-mediated disorders of the body, brain and eye, announced fourth quarter and full-year 2020 financial results and business highlights.

Recent Business Highlights

Annexon continues to make strong progress in advancing its broad and deep pipeline and clinical programs across a range of potential indications. Recent highlights include:

- **ANX005 in Guillain-Barré Syndrome (GBS).** In March 2021, the company completed evaluation of its drug-drug interaction (DDI) study of ANX005 co-administered with Intravenous Immunoglobulin (IVIg) in 14 patients with GBS. The DDI study was conducted to evaluate the safety and tolerability of ANX005 and IVIg co-administration in GBS patients, and measured pharmacokinetics (PK) and pharmacodynamics (PD) of ANX005 when administered in combination with IVIg. IVIg, though not FDA-approved in the United States for GBS, is currently the standard of care for GBS. Initial results from the DDI study included:
    - Co-administration of IVIg-ANX005 was well-tolerated.
    - Co-administration of IVIg-ANX005 achieved full C1q target engagement, and C1q suppression was maintained within the targeted range.
    - The open-label DDI study was not placebo-controlled or powered for statistical significance on efficacy measures. A number of key GBS outcome measures were recorded from baseline, and early improvement was observed in GBS patients, including increased muscle strength, decreased neurofilament light chain (NfL) and improved GBS disability score.

Full results from the DDI study are expected to be submitted to a peer-reviewed forum in 2021. A placebo-controlled Phase 2/3 trial is ongoing to evaluate the efficacy of ANX005 monotherapy in improving disability in GBS patients. Data from the Phase 2/3 trial is anticipated in 2023.

- **ANX007 in Geographic Atrophy (GA).** In February 2021, the company initiated a Phase 2 trial evaluating the efficacy of ANX007 in reducing the area of GA as evaluated by fundus autofluorescence (FAF) in patients with GA, which includes monthly and every other month dosing of ANX007. Data from this trial is anticipated in 2023.

- **In February 2021, Annexon appointed William H. Carson, M.D. to the Board of Directors.** Concurrent with Dr. Carson’s appointment, Thomas G. Wiggans was appointed as Annexon’s chairman.

“We continue to make progress against our vision of building a leading, multi-faceted complement therapeutics company with an innovative portfolio for a broad range of autoimmune, neurodegenerative and ophthalmic diseases,” said Douglas Love, Esq., president and chief executive officer of Annexon. “The DDI data gives us further confidence in ANX005. We are rapidly advancing multiple Phase 2 clinical programs across a diverse set of potential indications, and accelerating development of a number of innovative, next generation product candidates. This clinical momentum coupled with our strong capital position positions us well to drive value in 2021 and beyond.”

Fourth Quarter and Full-Year 2020 Financial Results

- **Cash and cash equivalents and short-term investments:** Cash and cash equivalents and short-term investments were $351.2 million as of December 31, 2020.

- **Research and development (R&D) expenses:** R&D expenses were $18.0 million for the quarter ended December 31, 2020 compared to $6.8 million for the quarter ended December 31, 2019. R&D expenses were $49.3 million for the year ended December 31, 2020 compared to $24.5 million for the year ended December 31, 2019.

- **General and administrative (G&A) expenses:** G&A expenses were $5.2 million for the quarter ended December 31, 2020 compared to $2.3 million for the quarter ended December 31, 2019. G&A expenses were $14.2 million for the year ended December 31, 2020 compared to $8.0 million for the year ended December 31, 2019.

- **Net loss:** Net loss was $23.2 million for the quarter ended December 31, 2020 compared to $8.9 million for the quarter ended December 31, 2019. Net loss was $63.4 million for the year ended December 31, 2020 compared to $37.2 million

for the year ended December 31, 2019.

About Annexon, Inc.

Annexon is a clinical-stage biopharmaceutical company developing a pipeline of novel therapies for patients with classical complement-mediated disorders of the body, brain and eye. The company's pipeline is based on its platform technology addressing well-researched classical complement-mediated autoimmune and neurodegenerative disease processes, both of which are triggered by aberrant activation of C1q, the initiating molecule of the classical complement pathway. Annexon is deploying a disciplined, biomarker-driven strategy designed to select indications, identify patients and to measure target engagement and response to treatment with its drug candidates. 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," "target," "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: advancement of the company's clinical and preclinical programs; timing of data from clinical trials and submission of data to peer-reviewed forums; confidence in the company's product candidates; the company's ability to drive value in 2021 and beyond; and the implementation of the company's business model and strategic plans for its business and product candidates, including potential treatment indications and additional indications that the company may pursue. 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.

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

	Three Months Ended December 31,		Year Ended December 31,	
	2020	2019	2020	2019
	(unaudited)	(unaudited)		
Operating expenses:				
Research and development (1)	$ 17,992	$ 6,795	$ 49,271	$ 24,524
General and administrative (1)	5,199	2,334	14,198	7,994
Total operating expenses	23,191	9,129	63,469	32,518
Loss from operations	(23,191)	(9,129)	(63,469)	(32,518)
Loss on remeasurement of redeemable convertible preferred stock liability	—	—	—	(5,670)
Other (expense) income, net	(7)	188	57	1,009
Net loss before taxes	(23,198)	(8,941)	(63,412)	(37,179)
Provision for income taxes	(5)	1	—	4
Net loss	(23,193)	(8,942)	(63,412)	(37,183)
Accretion on redeemable convertible preferred stock	—	(280)	(705)	(1,095)
Deemed dividend – beneficial conversion feature on redeemable convertible preferred stock	—	—	(6,219)	—
Net loss attributable to common stockholders	$ (23,193)	$ (9,222)	$ (70,336)	$ (38,278)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.61)	$ (21.26)	$ (4.15)	$ (88.30)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	38,157,618	433,749	16,962,398	433,493
(1) Includes the following stock-based compensation expense:				
Research and development	990	230	2,274	713
General and administrative	1,001	294	2,614	1,324

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

	December 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 268,565	$ 43,931
Short-term investments	82,641	—
Prepaid expenses and other current assets	2,805	1,475
Total current assets	354,011	45,406
Property and equipment	1,935	2,138
Other long-term assets	—	2,354
Total assets	$ 355,946	$ 49,898
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 3,734	$ 2,371
Accrued liabilities	6,497	2,194
Deferred rent, current	391	366
Total current liabilities	10,622	4,931
Deferred rent	1,046	1,437
Total liabilities	11,668	6,368
Redeemable convertible preferred stock	—	143,984
Stockholders' Equity (Deficit):		
Preferred stock	—	—
Common stock	38	4
Additional paid-in capital	510,309	2,202
Accumulated other comprehensive loss	(77)	(80)
Accumulated deficit	(165,992)	(102,580)
Total stockholders' equity (deficit)	344,278	(100,454)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	$ 355,946	$ 49,898

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