Annexon Reports Significant Progress with its Priority Programs and Third Quarter 2023 Financial Results

November 13, 2023

Company Prioritizes Greatest Near-term Value-Driving Programs: ANX005 for Guillain-Barré Syndrome (GBS), ANX007 for Geographic Atrophy (GA) and First-in-Kind Complement Small Molecule, ANX1502

ANX005 Phase 3 Pivotal Data in GBS On Track for First Half of 2024

ANX007 Awarded First-Ever PRIME Designation for the Treatment of GA; Global Regulatory Interactions Ongoing to Advance Phase 3 Program

ANX1502 Phase 1 Data on Track for Q4 2023

Focused Operations and Resources Support Cash Runway into Q2 2025

BRISBANE, Calif., Nov. 13, 2023 (GLOBE NEWSWIRE) -- Annexon, Inc. (Nasdaq: ANNX), a clinical-stage biopharmaceutical company developing a new class of complement-based medicines for people living with devastating inflammatory-related diseases, today highlighted portfolio progress and reported third quarter 2023 financial results.

"As the leading company focused on stopping C1q from initiating and driving harmful inflammation where it starts on diseased tissue, we're highly encouraged by the consistency of the clinical data demonstrating rapid and meaningful functional benefit across multiple disease areas," said Douglas Love, president and CEO of Annexon. "With increasing regulatory recognition of our data in GBS and GA in particular, and the potential of these programs to offer significant therapeutic advantages over existing treatments, we are sharply focused on bringing these classical complement therapies to patients as swiftly as possible while also intentionally advancing our first-in-kind classical complement small molecule program in an array of autoimmune conditions. As a result, we have aligned our efforts and resources on our three priority programs to drive maximum value for patients and stakeholders in the near-to-mid term."

Recent Clinical Program Updates

- **Continued Clinical and Regulatory Progress for ANX005 Pivotal Program in Guillain-Barré Syndrome (GBS):** In the third quarter, Annexon announced that the European Medicines Agency (EMA) granted orphan drug designation to ANX005 for the treatment of GBS. EMA orphan drug designation requires that a novel rare disease therapeutic demonstrates the potential for significant benefit over available therapies. For ANX005, the EMA's designation was based on a meta-analysis of past studies with ANX005 and intravenous immunoglobulin (IVIg), demonstrating notable, early improvement in muscle strength with ANX005 that translated into observable gains in health status, including a reduction in the need of mechanical ventilation. Importantly, Annexon also announced that it has achieved target enrollment of 225 patients in the randomized, double-blind, placebo-controlled Phase 3 trial of ANX005 in patients with GBS. Coupled with prior FDA alignment on the study's primary endpoint and statistical analysis plan, this enrollment milestone enables the company to deliver topline Phase 3 pivotal results in the first half of 2024.
- **EMA PRIME Designation Granted to ANX007 for the Treatment of Geographic Atrophy (GA):** Also in the third quarter, Annexon announced that EMA granted Priority Medicine (PRIME) designation to ANX007 for the treatment of GA secondary to age-related macular degeneration (AMD). EMA granted this designation, which provides enhanced support to accelerate development for priority medicines that target an unmet need, based on the Phase 2 ARCHER trial data that showed a consistent, durable, time and dose-dependent preservation of visual function in patients with GA, as well as preclinical data supporting the protective mechanism of ANX007 against photoreceptor damage and loss. ANX007 is the first therapeutic candidate to receive EMA PRIME designation for GA, and the first ophthalmology product awarded the designation that is not targeting a rare disease or is not a cell or gene therapy. PRIME designation is a competitive process, with EMA awarding PRIME to only approximately a quarter of all requests.
- **Additional Analyses from ARCHER Presented at the American Academy of Ophthalmology (AAO) Conference:** At AAO in November, additional analyses from the ARCHER Phase 2 trial in patients with GA were presented supporting time and dose-dependent protection from vision loss. In a new analysis of best corrected visual acuity (BCVA) in patients with ≥15 letter vision loss (loss of three lines of vision on a standardized eye chart), ANX007's treatment effect increased over the course of the on-treatment portion of the study. In that regard, the second six months of ANX007 treatment provided greater protection against the loss of visual function than the first six months compared to sham, suggesting that ANX007 may provide a growing and durable treatment effect over time. In addition, topline data from the final ARCHER study of the full six-month off-treatment period were presented, showing that ANX007's protection against BCVA ≥15 letter vision loss demonstrated during the treatment period was reversed once ANX007 treatment was discontinued. These results underscore the on-treatment effect of ANX007 therapy and further support the strong and consistent benefit demonstrated of preserving vision as measured by BCVA ≥15 letter vision loss. More than 25 GA Phase 2 and Phase 3 trials have been conducted, and none have shown statistically significant preservation of BCVA ≥15 letter vision loss, nor a significant false

positive outcome, utilizing this objective and well-established endpoint.

- **Results of Single-Arm, Phase 1b Study of ANX009 Show that the Classical Pathway is a Key Driver of Complement Activation and Consumption in Patients with Active Lupus Nephritis (LN):** At the American Society of Nephrology's Kidney Week 2023 conference in November, data were presented from the Phase 1b signal-finding trial of ANX009, which used a precision medicine approach to identify patients with LN who have high baseline complement activity. LN is an autoimmune disease for which pathogenic anti-C1q antibodies (PACAs) enhance C1q activity and uniquely amplify classical complement-mediated kidney inflammation and damage. Initial results showed subcutaneous ANX009 was well tolerated and demonstrated plasma C1q target engagement and complement inhibition. Remarkably, inhibition of C1q rapidly increased free/circulating PACA levels (consistent with decreased deposition in the kidney) and inhibited all downstream markers of complement consumption and activation (C4, C3 and C5). These results indicate that C1q and the classical pathway are key drivers of complement activation in LN, independent of the alternative and lectin pathways, and that PACAs are a unique component of the classical complement activation pathway. Consistent with the short duration of this signal-finding study (3 weeks), changes in urinary protein excretion were not observed as anticipated.

Key Near-Term Anticipated Milestones

Priority Programs

- **ANX005 in GBS:** Initial topline results from the Phase 3 pivotal trial of ANX005 in patients with GBS are anticipated during the first half of 2024. To enable focus on priority programs, Annexon will not conduct an R&D Day in 2023, and instead plans to host an event focused on the burden of disease, current treatment paradigm and market opportunity for GBS in the first half of 2024.
- **ANX007 in GA:** Interactions with U.S. and EU regulatory authorities on a global Phase 3 pivotal program for ANX007 are ongoing, with plans to provide an update by year-end 2023.
- **ANX1502 in autoimmune diseases:** Results from the single and multiple-ascending dose Phase 1 trial in healthy volunteers are expected to be reported by year-end 2023.

Next Wave Programs

- **ANX005 in Amyotrophic Lateral Sclerosis (ALS):** Following encouraging preliminary results which showed slowing of disease progression, full on-treatment data from the Phase 2a trial are expected by early 2024.
- **ANX005 in Huntington's Disease (HD):** Annexon is assessing the initiation of a planned late-stage trial in HD in 2024 as the company prioritizes near-term pivotal development activities for GBS, GA and ANX1502.

Third Quarter 2023 Financial Results

- **Cash and operating runway:** Cash and cash equivalents and short-term investments were $165.3 million as of September 30, 2023. Annexon continues to expect its cash, cash equivalents and marketable securities as of September 30, 2023, to be sufficient to fund the company's planned operating expenses into the second quarter of 2025.
- **Research and development (R&D) expenses:** R&D expenses were $27.9 million for the quarter ended September 30, 2023, reflecting the advancement of the company's priority programs, including GBS, GA and ANX1502, compared to $27.9 million for the quarter ended September 30, 2022.
- **General and administrative (G&A) expenses:** G&A expenses were $6.9 million for the quarter ended September 30, 2023, compared to $8.2 million for the quarter ended September 30, 2022.
- **Net loss:** Net loss was $32.5 million or $0.43 per share for the quarter ended September 30, 2023, compared to $35.1 million or $1.42 per share for the quarter ended September 30, 2022.

About Annexon

Annexon Biosciences (Nasdaq: ANNX) is a clinical-stage biopharmaceutical company utilizing a distinct scientific approach to stop C1q and all inflammatory aspects of classical complement pathway activation before it starts. As the only company solely focused on shutting down C1q, Annexon is developing a fit-for-purpose pipeline of therapeutics designed to provide meaningful benefits across multiple diseases of the body, brain and eye. With proof-of concept data in both Guillain-Barré syndrome and geographic atrophy, Annexon is rigorously advancing its mid-to late-stage clinical trials to bring their potential treatments to patients as quickly as possible. To learn more visit 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; timing of program updates and enrollment completion for ANX005, ANX007 and ANX1502; 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; potential of ANX007 to support strong beneficial impact on preserving vision; 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

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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,	
	2023	**2022**	**2023**	**2022**
Operating expenses:				
Research and development (1)	$ 27,893	$ 27,862	$ 90,489	$ 83,966
General and administrative (1)	6,888	8,207	23,225	24,938
Total operating expenses	34,781	36,069	113,714	108,904
Loss from operations	(34,781)	(36,069)	(113,714)	(108,904)
Interest and other income, net	2,299	1,015	7,368	1,340
Net loss	$ (32,482)	$ (35,054)	$ (106,346)	$ (107,564)
Net loss per share, basic and diluted	$ (0.43)	$ (0.51)	$ (1.42)	$ (2.21)
Weighted-average shares used in computing net loss per share, basic and diluted	75,342,495	68,652,859	74,815,274	48,710,433

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

Research and development	$ 2,243	$ 2,433	$ 6,801	$ 6,509
General and administrative	$ 2,306	$ 2,478	$ 7,015	$ 7,174

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

	September 30, 2023 (Unaudited)	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 133,159	$ 140,020
Short-term investments	32,112	102,637

Prepaid expenses and other current assets	3,898	5,441
Total current assets	169,169	248,098
Restricted cash	1,032	1,032
Property and equipment, net	15,310	16,838
Operating lease right-of-use assets	18,305	19,128
Total assets	$ 203,816	$ 285,096
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 4,809	$ 7,416
Accrued liabilities	10,490	13,448
Operating lease liabilities, current	1,701	1,316
Other current liabilities	170	180
Total current liabilities	17,170	22,360
Operating lease liabilities, non-current	29,807	31,542
Total liabilities	46,977	53,902
Stockholders' equity:		
Common stock	53	48
Additional paid-in capital	701,517	669,780
Accumulated other comprehensive loss	(123)	(372)
Accumulated deficit	(544,608)	(438,262)
Total stockholders' equity	156,839	231,194
Total liabilities and stockholders' equity	$ 203,816	$ 285,096