Annexon Reports First Quarter 2025 Financial Results, Portfolio Progress and Key Anticipated Milestones

May 12, 2025

FDA Meeting for Tanruprubart (formerly ANX005), the First Potential Targeted Therapy for GBS, Scheduled for Second Quarter 2025 Ahead of Planned BLA Submission

Open-Label Tanruprubart FORWARD Study Designed to Broaden Patient and Healthcare Community Experience in North America and Europe, Initiating in Second Quarter 2025

Accelerated Enrollment in Phase 3 ARCHER II Trial on Pace for Completion in Third Quarter 2025 for ANX007, the First Potential Treatment for Dry AMD with GA; Pivotal Topline Data Expected in the Second Half of 2026

Completion of Proof-of-Concept Trial for First-in-Kind Oral C1s Inhibitor ANX1502 in Cold Agglutin Disease Anticipated Mid-2025; Potential to Disrupt the Current Treatment of Antibody-Mediated Autoimmune Diseases

$263.7 million in Cash, Cash Equivalents, and Short-term Investments as of March 31, 2025 Funds Late-Stage Milestones for Lead Programs and Anticipated Runway into Second Half 2026

BRISBANE, Calif., May 12, 2025 (GLOBE NEWSWIRE) -- Annexon, Inc. (Nasdaq: ANNX), a biopharmaceutical company advancing a late-stage clinical platform of novel therapies for people living with devastating classical complement-mediated neuroinflammatory diseases of the body, brain, and eye, today highlighted portfolio progress and reported first quarter 2025 financial results.

“Our innovative C1 platform has yielded multiple wholly owned late-stage programs that have been shown to stop harmful neuroinflammation and lead to positive outcomes for patients across an array of diseases,” said Douglas Love, president and chief executive officer of Annexon. “Our most advanced program, tanruprubart, is approaching filing for the treatment of Guillain-Barré Syndrome (GBS) having consistently demonstrated rapid and sustained functional improvements in multiple placebo-controlled trials. Given the decades-long void of innovation, GBS remains a high unmet need without FDA-approved therapies or substantial evidence of effectiveness from the current standard of care, and we are eager to continue our dialogue with the FDA during our upcoming meeting this quarter in advance of our planned BLA submission. Furthermore, we are excited for the launch this quarter of the open-label FORWARD study designed to provide North American and European physicians and patients investigational access and experience with tanruprubart’s single infusion approach to tackling GBS.”

Mr. Love continued, “Our second late-stage asset, ANX007, is poised to be the first vision-preserving treatment for dry age-related macular degeneration (AMD) with geographic atrophy (GA) globally, offering the potential to benefit more than eight million patients worldwide. With positive engagement by the retina community, we are on an accelerated pace to complete enrollment of the ongoing Phase 3 ARCHER II trial in the third quarter and deliver pivotal topline data in the second half of 2026. Finally, we anticipate completing the proof-of-concept (POC) trial for our oral small molecule ANX1502 in mid-2025, further characterizing its initial drug profile in patients with autoimmune disease.”

Mr. Love concluded, “With continued strong strategic execution and runway into the second half of 2026, we are well-positioned to drive immense near to mid-term value and fulfill our mission of helping millions of patients live their best lives.”

Recent Corporate and Clinical Program Updates

Flagship Programs

Tanruprubart (ANX005) in Guillain-Barré Syndrome (GBS): First-in-kind monoclonal antibody designed to block C1q with a single infusion to halt ongoing neuroinflammation and nerve damage in the acute phase of disease. GBS is a rare, neuromuscular emergency that affects approximately 150,000 people worldwide each year.

- Strong therapeutic potential underscored by consistent demonstration of rapid and durable functional improvements and a differentiated safety profile across multiple placebo-controlled clinical studies.
- There are no FDA-approved therapies for GBS and no substantial evidence of effectiveness from the current standards of care therapy used in GBS. The rare and acute nature of GBS has shaped our clinical development program conducted primarily in Southeast Asia to generate a comprehensive data package. This package includes successful placebo-controlled POC and Phase 3 data, Real-World Evidence indirect comparison data of tanruprubart’s treatment effect versus current standards of care, and drug-drug interaction safety data with tanruprubart with current standard of care.
- To further our strategic development plan, preparing to initiate the open-label tanruprubart FORWARD study, measuring pharmacokinetics, pharmacodynamics, early efficacy in week 1, and safety in up to 30 subjects in the United States, Canada, and Europe, which is designed to broaden Western patient, physician and healthcare community experience.
- Real-World Evidence study to be featured in an oral presentation on Monday May 19, 2025 at the upcoming 2025 Peripheral Nerve Society (PNS) Annual Meeting taking place May 17-20, 2025 in Edinburgh, UK. Additional poster presentations will also reinforce early and durable benefits of tanruprubart including improvement in quality of life for

patients with GBS.

- **Next Milestone:** Initiation of the tanruprubart FORWARD study expected in the second quarter of 2025. FDA meeting with the Center for Drug Evaluation and Research (CDER) scheduled for the second quarter of 2025 ahead of planned BLA submission.

ANX007 in Dry Age-Related Macular Degeneration (AMD) Patients with Geographic Atrophy (GA): First-in-kind, non-pegylated antigen-binding fragment (Fab) designed to block C1q and the classical complement cascade locally in the eye. Dry AMD with GA is a leading cause of blindness that affects more than eight million patients worldwide with no approved therapies targeting the preservation of vision.

- Global registration path established with U.S. and European regulators supports potential of ANX007 to be the first treatment approved in both Europe and the U.S. for protection of vision in patients who have dry AMD with GA.
- ARCHER II is a global, pivotal, sham-controlled, double-masked Phase 3 trial expected to enroll approximately 630 patients who have dry AMD with GA.
- Phase 2 ARCHER data showing significant preservation of vision and central retinal photoreceptors necessary for visual acuity presented at the 2025 Association for Research in Vision and Ophthalmology (ARVO) Annual Meeting and at the 2025 Retina World Congress.
- **Next Milestone:** Phase 3 ARCHER II trial enrollment expected to be completed in third quarter of 2025; top line data expected in second half of 2026.

ANX1502 for Autoimmune Conditions: First-in-kind oral small molecule inhibiting the activated form of C1s, an enzyme carried by C1q to initiate the classical cascade, has the potential to offer the advantages of selective upstream classical complement inhibition with the convenience and flexibility of oral administration.

- Ongoing enrollment in open-label, single arm, proof-of-concept study characterizing the pharmacokinetics, pharmacodynamics, dosing regimen, safety and initial efficacy of enteric-coated tablets of ANX1502 in up to seven patients with cold agglutinin disease (CAD).
- **Next Milestone:** POC trial completion in up to seven CAD patients anticipated in mid-2025.

First Quarter 2025 Financial Results

- **Cash and operating runway:** Cash and cash equivalents and short-term investments were $263.7 million as of March 31, 2025. Annexon continues to expect its cash, cash equivalents and short-term investments as of March 31, 2025, to be sufficient to fund the company's planned operating expenses and late-stage milestones for its lead programs into the second half of 2026.
- **Research and development (R&D) expenses:** R&D expenses were $48.2 million for the quarter ended March 31, 2025, reflecting the advancement of the Company's priority programs, including GBS, GA and ANX1502, compared to $21.0 million for the quarter ended March 31, 2024.
- **General and administrative (G&A) expenses:** G&A expenses were $9.2 million for the quarter ended March 31, 2025, compared to $7.6 million for the quarter ended March 31, 2024.
- **Net loss:** Net loss was $54.4 million or $0.37 per share for the quarter ended March 31, 2025, compared to $25.2 million or $0.21 per share for the quarter ended March 31, 2024.

About Annexon

Annexon Biosciences (Nasdaq: ANNX) is developing therapeutics that stop classical complement-driven neuroinflammation as first-in-kind treatments for millions of people living with serious neuroinflammatory diseases of the body, brain and eye. Our novel scientific approach focuses on C1q, the initiating molecule of classical complement's potent inflammatory pathway that when misdirected can lead to tissue damage and loss in a host of diseases. By targeting C1q, our immunotherapies are designed to stop this neuroinflammatory cascade before it starts. Our pipeline spans three diverse therapeutic areas – autoimmunity, neurodegeneration and ophthalmology – and includes targeted investigational drug candidates designed to address the unmet needs of nearly 10 million people worldwide. Annexon's mission is to deliver game-changing therapies to patients so that they can live their best lives. 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," "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: the potential therapeutic benefit of ANX005, if approved, compared to existing therapies; anticipated timing of the pre-BLA meeting and BLA submission for ANX005; potential benefit of ANX005, if approved, compared to existing therapies; the design, objectives and timing of the open-label tanruprubart FORWARD study; the company's ability to achieve regulatory approval for ANX005; the potential therapeutic benefit of ANX007; timing and pace of

completion of enrollment and results from the Phase 3 ARCHER II trial; ANX007's distinct potential neuroprotective mechanism of action and potential to provide protection from vision loss; the potential for ANX007 to be the first drug approved in Europe and the U.S. for dry AMD with GA; timing of proof-of-concept trial for ANX1502 in cold agglutin disease; the potential for ANX1502 to disrupt the current treatment antibody-mediated autoimmune diseases; the company's ability to commercialize its product candidates, if approved; continued development of ANX007 and ANX1502; anticipated cash runway into the second half of 2026; the potential benefits from treatment with anti-C1q therapy; 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 final results from the Phase 3 ARCHER II trial; 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 (Unaudited)
(in thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2025	**2024**
Operating expenses:		
Research and development (1)	$ 48,179	$ 20,963
General and administrative (1)	9,226	7,609
Total operating expenses	57,405	28,572
Loss from operations	(57,405)	(28,572)
Interest and other income, net	3,049	3,396
Net loss	$ (54,356)	$ (25,176)
Net loss per share, basic and diluted	$ (0.37)	$ (0.21)
Weighted-average shares used in computing net loss per share, basic and diluted	148,108,809	122,673,202

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

Research and development	$ 2,829	$ 2,282
General and administrative	$ 2,249	$ 2,378

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

	March 31, 2025	December 31, 2024

Assets		
Current assets:		
Cash and cash equivalents	$ 97,122	$ 49,498
Short-term investments	166,574	262,519
Prepaid expenses and other current assets	4,466	4,444
Total current assets	268,162	316,461
Restricted cash	1,032	1,032
Property and equipment, net	12,190	12,638
Operating lease right-of-use assets	16,346	16,705
Other non-current assets	5,297	3,235
Total assets	$ 303,027	$ 350,071
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 10,437	$ 10,426
Accrued and other current liabilities	20,494	17,568
Operating lease liabilities, current	2,616	2,518
Total current liabilities	33,547	30,512
Operating lease liabilities, non-current	25,692	26,454
Total liabilities	59,239	56,966
Stockholders' equity:		
Common stock	109	109
Additional paid-in capital	1,008,825	1,003,685
Accumulated other comprehensive income (loss)	(91)	10
Accumulated deficit	(765,055)	(710,699)
Total stockholders' equity	243,788	293,105
Total liabilities and stockholders' equity	$ 303,027	$ 350,071