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AbbVie Announces Results from Phase 2 Study Evaluating Rovalpituzumab Tesirine (Rova-T) for Third-Line Treatment of Patients with DLL3-Expressing Relapsed/Refractory Small Cell Lung Cancer

- AbbVie will not seek accelerated approval for Rova-T in third-line relapsed/refractory small cell lung cancer (SCLC)
- Rova-T demonstrated single agent responses in advanced SCLC patients
- Ongoing Phase 3 studies, MERU and TAHOE, will continue to investigate Rova-T in first- and second-line SCLC
- Safety data in the TRINITY study were consistent with previously reported studies of Rova-T
- Full data have been submitted to the 2018 American Society of Clinical Oncology (ASCO) Annual Meeting

NORTH CHICAGO, Ill., March 22, 2018 /PRNewswire/ -- AbbVie (NYSE:ABBV), a global research and development-based biopharmaceutical company, today announced that after consulting with the U.S. Food and Drug Administration (FDA), it will not seek accelerated approval for Rova-T in third-line relapsed/refractory (R/R) small cell lung cancer (SCLC) based on magnitude of effect across multiple parameters in this single-arm study.

"We continue to believe Rova-T has potential for patients with small cell lung cancer and other DLL3-expressing cancers," said Mike Severino, M.D., executive vice president of research and development and chief scientific officer, AbbVie. "Although the results from the study were not what we hoped for, we look forward to receiving data from the ongoing Phase 3 studies in the first- and second-line settings and remain committed to developing Rova-T for the treatment of patients with small cell lung cancer."

Summary of Investigator Assessed Best Overall Response Rate, Independent Review Committee (IRC) Assessed Objective Response Rate, Duration of Response and Overall Survival in Third-Line SCLC Patients with High DLL3 Expression (N = 177)*

	DLL3 High 3L (N = 177)
Investigator Assessed Outcome	
Best Overall Response Rate[a] (95% CI)	29% (22%, 36%)
IRC Assessed Outcomes	
Objective Response Rate (by RECIST criteria – v1.1)[b] (95% CI)	16% (11%, 22%)
Duration of Objective Response (months)	4.1

Median (months) (95% CI)	(3.0, 4.2)
Overall Survival	
Median (months) (95% CI)	5.6 (4.9, 6.8)
Probability of Subjects Alive at 12 months (95% CI)[c]	17.5% (10.8%, 25.5%)

**Data represent 74 percent of the TRINITY study population with high DLL3 expression*

[a] Best overall response is defined as a subject with a response of complete response (CR) or partial response (PR) at any time prior to receiving any subsequent anticancer therapy.

[b] Objective response is defined as a subject with a response of complete response (CR) or partial response (PR) prior to receiving any subsequent anticancer therapy, with confirmation of CR or PR at least 4 weeks (28 days) from the initial determination per RECIST v1.1.

[c] Based on Kaplan-Meier estimate.

In the study, the most common treatment-emergent adverse events were fatigue (38 percent), photosensitivity reaction (36 percent), pleural effusion (32 percent), edema peripheral (31 percent), decreased appetite (30 percent), nausea (26 percent), dyspnea (25 percent), thrombocytopenia (25 percent), constipation (22 percent), vomiting (17 percent), anemia (17 percent), hypoalbuminemia (16 percent), and cough (16 percent). Grade three and higher severe toxicities ≥ 5 percent were thrombocytopenia (11 percent), photosensitivity reaction (7 percent) and pleural effusion (5 percent).

About the Phase 2 TRINITY Study

TRINITY is a multicenter, open-label, single-arm, Phase 2 study of Rova-T in DLL3-expressing small cell lung cancer (SCLC) patients with relapsed/refractory (R/R) disease after receiving at least two previous regimens, including at least one platinum-based regimen. The primary objective was to investigate the efficacy of Rova-T as third-line and later treatment for R/R DLL3-expressing SCLC. Secondary objectives included assessment of safety and tolerability, pharmacokinetics, RECIST-assessed progression-free survival, duration of response and clinical benefit rate.

About Rovalpituzumab Tesirine (Rova-T)

Rova-T is an investigational antibody-drug conjugate targeting the cancer-stem cell-associated delta-like protein 3 (DLL3)[1], which is expressed in more than 80 percent of small cell lung cancer (SCLC) patient tumors, where it is prevalent on tumor cells, including cancer stem cells, but not present in healthy tissue.[2] Rova-T combines a targeted antibody that delivers a cytotoxic agent directly to the DLL3-expressing cancer cells while minimizing toxicity to healthy cells. Rova-T is under investigation as a third-line treatment in SCLC.[2] The expression of DLL3 suggests Rova-T may be useful across multiple tumor types, including metastatic melanoma, glioblastoma multiforme and some prostate, pancreatic and colorectal cancers.[2]

Rova-T is an investigational compound and its efficacy and safety have not been established by the FDA or any other health authority.

About AbbVie

AbbVie is a global, research-driven biopharmaceutical company committed to developing innovative advanced therapies for some of the world's most complex and critical conditions. The company's mission is to use its expertise, dedicated people and unique approach to innovation to markedly improve treatments across four primary therapeutic areas: immunology, oncology, virology and neuroscience. In more than 75 countries, AbbVie employees are working every day to advance health solutions for people around the world. For more information about AbbVie, please visit us at www.abbvie.com. Follow @abbvie on Twitter, Facebook or LinkedIn.

Forward-Looking Statements

Some statements in this news release are, or may be considered, forward-looking statements for

purposes of the Private Securities Litigation Reform Act of 1995. The words "believe," "expect," "anticipate," "project" and similar expressions, among others, generally identify forward-looking statements. AbbVie cautions that these forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially from those indicated in the forward-looking statements. Such risks and uncertainties include, but are not limited to, challenges to intellectual property, competition from other products, difficulties inherent in the research and development process, adverse litigation or government action, and changes to laws and regulations applicable to our industry. Additional information about the economic, competitive, governmental, technological and other factors that may affect AbbVie's operations is set forth in Item 1A, "Risk Factors," of AbbVie's 2017 Annual Report on Form 10-K, which has been filed with the Securities and Exchange Commission. AbbVie undertakes no obligation to release publicly any revisions to forward-looking statements as a result of subsequent events or developments, except as required by law.

[1] Saunders L. R. et al. A DLL3-targeted antibody-drug conjugate eradicates high-grade pulmonary neuroendocrine tumor-initiating cells in vivo. Sci. Transl. Med. 2015;7(302): 1-13.

[2] ClinicalTrials.gov (2016). Study of Rovalpituzumab Tesirine (SC16LD6.5) for Third-line and Later Treatment of Subjects With Relapsed or Refractory Delta-Like Protein 3-Expressing Small Cell Lung Cancer (TRINITY). Accessed March 21, 2018. https://clinicaltrials.gov/ct2/show/NCT02674568?term=SC16LD6.5&rank=2.

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