Elotuzumab Progression-Free Survival Data from Phase 2 Study of Patients with Previously-Treated Multiple Myeloma Presented at 54th American Society of Hematology (ASH) Annual Meeting

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- In patients treated with elotuzumab 10 mg/kg plus lenalidomide and low-dose dexamethasone, median progression-free survival (PFS) was not reached after 20.8 months of follow up and the objective response rate (ORR) was 92%
- In patients treated with elotuzumab 20 mg/kg plus lenalidomide and low-dose dexamethasone, median PFS was 18.6 months and ORR was 76%
- Safety profile consistent with results previously reported
- Presentation selected for Highlights of ASH
- Two Phase 3 studies of elotuzumab ongoing in patients with newly-diagnosed and previously-treated multiple myeloma

PRINCETON, N.J. & ABBOTT PARK, Ill.--(BUSINESS WIRE)--Bristol-Myers Squibb Company (NYSE: BMY) and Abbott (NYSE: ABT) today announced results from a small, randomized Phase 2, open-label study in patients with previously-treated multiple myeloma that evaluated two doses of elotuzumab (10 mg/kg and 20 mg/kg) in combination with lenalidomide and low-dose dexamethasone. In the 10 mg/kg arm, median progression-free survival (PFS), or the time without disease progression or death, was not reached after 20.8 months of follow up (N=36) and the objective response rate (ORR) was 92%. Of patients who received elotuzumab at a dose of 20 mg/kg, median PFS was 18.6 months (N=37) and ORR was 76%.

The safety data are consistent with previously-reported results for elotuzumab. Overall, 78% of patients experienced ≥1 treatment emergent grade ≥3 events. The most common were lymphopenia (19%), neutropenia (18%), thrombocytopenia (16%), anemia (12%), leukopenia (10%), hyperglycemia (10%), pneumonia (7%), diarrhea (7%), fatigue (7%), and hypokalemia (6%). Two deaths occurred on study (multiple adverse events [n=1; pneumonia, multiple organ failure and sepsis]; disease progression [n=1]). Infusion reactions (any grade) were reported in 14% of patients. Second primary malignancies were reported in four patients and were deemed as unrelated to elotuzumab.

These results were presented today during an oral session at the 54th Annual Meeting of the American Society of Hematology (ASH) in Atlanta and selected for presentation at Highlights of ASH.

“Multiple myeloma is the second most common blood cancer and remains incurable despite advances in treatment options over the last decade. In fact, there remains a high unmet medical need for patients, as almost all will eventually relapse and become refractory to currently available therapies,” said Paul G. Richardson, M.D. Clinical Director, Jerome Lipper Center for Multiple Myeloma, Dana-Farber Cancer Institute, lead author and principal investigator of the study. “The Phase 2 PFS data for elotuzumab presented today are encouraging and support further evaluation of this antibody in patients with multiple myeloma as part of large Phase 3 trials.”

Elotuzumab, an investigational immunotherapy, is a humanized monoclonal antibody that enhances immune cell mediated killing of multiple myeloma cells that have a surface protein called CS1. CS1 is a cell-surface glycoprotein that is highly expressed on myeloma cells.

“The data presented at ASH underscore Bristol-Myers Squibb’s dedication to seeking advances in care for patients with hematological malignancies,” said Brian Daniels, MD, senior vice president, Global Development and Medical Affairs, Research and Development, Bristol-Myers Squibb. “Elotuzumab, which is in Phase 3 development for multiple myeloma, is also an example of our commitment to develop immunotherapies and immuno-oncology approaches to help address areas of significant unmet medical need in a broad range of cancers.”
Two Phase 3 studies of elotuzumab in combination with lenalidomide and low-dose dexamethasone at a dose of 10 mg/kg are ongoing. The Phase 3 first-line multiple myeloma trial known as ELOQUENT-1 continues to enroll patients and the Phase 3 trial of patients with relapsed/refractory multiple myeloma known as ELOQUENT-2 is fully enrolled. A randomized Phase 2 study of bortezomib and dexamethasone with or without elotuzumab is also ongoing in patients with relapsed/refractory multiple myeloma.

About the Phase 2 Study

The primary endpoint of this Phase 2, randomized, multicenter, open-label study was ORR according to the International Myeloma Working Group (IMWG) response criteria. Patients were randomized 1:1 to receive elotuzumab either 10 or 20 mg/kg (IV infusion on days 1, 8, 15, and 22 of a 28-day cycle in the first 2 cycles and then days 1 and 15 of subsequent cycles), with lenalidomide 25 mg PO daily on days 1 to 21 and dexamethasone 40 mg PO weekly. Patients were treated until disease progression or unacceptable toxicity, if earlier.

About Multiple Myeloma

Multiple myeloma is a type of cancer that originates in the white blood cells. It is the second most common blood cancer with an annual incidence of more than 100,000 worldwide and a 5-year survival rate of 41% in newly-diagnosed patients. In 2012, it is estimated that more than 21,700 new cases will be diagnosed in the U.S. and that 10,710 people will die from the disease.

About Bristol-Myers Squibb

Bristol-Myers Squibb is a global biopharmaceutical company whose mission is to discover, develop and deliver innovative medicines that help patients prevail over serious diseases. For more information about Bristol-Myers Squibb, visit www.bms.com, or follow us on Twitter at http://twitter.com/bmsnews.

About Abbott

Abbott (NYSE: ABT) is a global, broad-based health care company devoted to the discovery, development, manufacturing and marketing of pharmaceuticals and medical products, including nutritionals, devices and diagnostics. The company employs approximately 91,000 people and markets its products in more than 130 countries.

Bristol-Myers Squibb Forward-Looking Statements

This press release contains “forward-looking statements” as that term is defined in the Private Securities Litigation Reform Act of 1995, regarding the research, development and commercialization of pharmaceutical products. Such forward-looking statements are based on current expectations and involve inherent risks and uncertainties, including factors that could delay, divert or change any of them, and could cause actual outcomes and results to differ materially from current expectations. No forward-looking statement can be guaranteed. Among other risks, there can be no guarantee clinical trials of the compound described in this release will support a regulatory filing or that the compound will receive regulatory approval or become a commercially successful product. Forward-looking statements in the press release should be evaluated together with the many uncertainties that affect Bristol-Myers Squibb’s business, particularly those identified in the cautionary factors discussion in Bristol-Myers Squibb’s Annual Report on Form 10-K for the year ended December 31, 2011, its Quarterly Reports on Form 10-Q, and Current Reports on Form 8-K. Bristol-Myers Squibb undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise.

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