November 19, 2013

Janssen Oncology Data to be Presented at 2013 American Society of Hematology (ASH) Annual Meeting

Findings Highlight Company's Growing Hematologic Area of Focus, Including Ibrutinib, Siltuximab and Daratumumab

Note: This release corresponds to ASH abstracts 525, 852, 2872, 4163, 505, 1806, 277, 378, 1986

RARITAN, NJ, November 19, 2013 - Janssen Research & Development, LLC (Janssen) announced that data related to three Janssen compounds have been selected for presentation at the 55th American Society of Hematology (ASH) Annual Meeting in New Orleans, LA. Nine pieces of company-sponsored research will be presented out of a total of nearly 50 abstracts involving Janssen hematology compounds. Data include presentations on the investigational use of ibrutinib, recently approved by the U.S. Food and Drug Administration; siltuximab, an investigational anti Interleukin-6 (IL-6) chimeric monoclonal antibody being studied in multicentric Castleman disease (MCD); and daratumumab, an investigational human CD38 monoclonal antibody being studied in multiple myeloma and other B-cell malignancies.

"Therapies for hematologic malignancies are the cornerstone of our broad oncology portfolio at Janssen R&D," said Peter F. Lebowitz, M.D., Ph.D., global oncology therapeutic area head, Janssen. "It's rewarding to have such a comprehensive array of data presented at ASH, across our oncology compounds, particularly as we look ahead to potential regulatory milestones for siltuximab and daratumumab, and following the recent U.S. FDA approval of ibrutinib."

List of Company-Sponsored Research to Be Presented

Ibrutinib
Ibrutinib data will be featured in more than 40 abstracts, including both company-sponsored research and investigator-initiated studies. The following studies sponsored by either Janssen or Pharmacyclics, Inc. have been selected for presentation:

- **Ibrutinib in combination with bendamustine and rituximab is active and tolerable in patients with relapsed/refractory CLL/SLL: final results of a phase 1b study. (Abstract 525)**
  Oral session: CLL: Therapy, Excluding Transplantation: Chemoimmunotherapy Clinical Trials. Monday, December 9 at 3:15 pm CST in Ernest N. Morial Convention Center, 220-222
- **Combining ibrutinib with rituximab, cyclophosphamide, doxorubicin, vincristine, and prednisone (R-CHOP): updated results from a phase 1b study in treatment-naïve patients with CD20-positive B-cell non-Hodgkin's lymphoma (NHL). (Abstract 852)**
  Oral session: Lymphoma: Therapy with Biological Agents, Excluding Pre-Clinical Models: Aggressive Lymphomas. Tuesday, December 10 at 8:45 am CST in Ernest N. Morial Convention Center, La Nouvelle Ballroom AB
- **Changing the treatment paradigm for previously treated chronic lymphocytic leukemia patients with del(17p) karyotype. (Abstract 2872)**
  Poster session: CLL: Therapy, Excluding Transplantation: Poster II. Sunday, December 8 at 6:30-8:30 pm CST in Ernest N. Morial Convention Center, Hall E
- **The Bruton's tyrosine kinase (BTK) inhibitor ibrutinib (PCI-32765) monotherapy demonstrates long-term safety and durability of response in chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) patients in an open-label extension study. (Abstract 4163)**
  Poster session: CLL: Therapy, Excluding Transplantation: Poster I. Monday, December 9 at 6:00-8:00 pm CST in Ernest N. Morial Convention Center, Hall E

Siltuximab
There are a total of three siltuximab abstracts scheduled for presentation at ASH, including both company-sponsored research and investigator-initiated studies. The following company-sponsored siltuximab data have been selected for presentation:

- **A multicenter, randomized, double-blind, placebo-controlled study of the efficacy and safety of siltuximab, an anti-interleukin-6 monoclonal antibody, in patients with multicentric Castleman's disease. (Abstract 505)**
  Oral session: Lymphoma: Therapy with Biological Agents, Excluding Pre-Clinical Models: Immunotherapy for Indolent Lymphomas. Monday, December 9 at 2:45-4:15 pm CST in Ernest N. Morial Convention Center, La Nouvelle Ballroom AB
- **An open-label, Phase 2, multicenter study of the safety of long-term treatment with siltuximab (an anti-interleukin-6 monoclonal antibody) in patients with multicentric Castleman's disease. (Abstract 1806)**
  Poster session: Lymphoma: Therapy with Biologic Agents, Excluding Pre-Clinical Models: Poster I. Saturday, December 7 at 5:30-7:30 pm CST in Ernest N. Morial Convention Center, Hall G

Daratumumab
A total of three daratumumab abstracts have been selected for presentation and were jointly supported by Janssen and Genmab A/S:

- **CD38-Targeted immunochemotherapy of multiple myeloma: preclinical evidence for its combinatorial use in lenalidomide and bortezomib refractory/intolerant MM patients. (Abstract 277)**
  Oral session: Myeloma: Pathophysiology and Pre-Clinical Studies, Excluding Therapy: Drug Resistance. Monday, December 9 at 7 am CST in Ernest N. Morial Convention Center, 391-392
- **Daratumumab, a novel human anti-CD38 monoclonal antibody, shows anti-tumor activity in mouse models of MCL, FL and CLL. (Abstract 378)**
  Oral session: Lymphoma: Pre-Clinical - Chemotherapy and Biologic Agents: Modulating the Immune System in Lymphoma. Monday, December 9 at 11:45 am CST in Ernest N. Morial Convention Center, 220-222
- **Preliminary safety and efficacy data of daratumumab in combination with lenalidomide and dexamethasone in relapsed or refractory multiple myeloma. (Abstract 1986)**
  Poster session: Myeloma: Therapy, Excluding Transplantation: Poster I. Saturday, December 7 at 5:30-7:30 pm CST in Ernest N. Morial Convention Center, Hall G

About Ibrutinib
Janssen Biotech, Inc. and Pharmacyclics, Inc. entered a collaboration and license agreement in December 2011 to jointly develop and commercialize ibrutinib. On November 13, 2013, the U.S. Food and Drug Administration granted approval for the use of ibrutinib in patients with mantle cell lymphoma (MCL) who have received at least one prior therapy. This indication is based on overall response rate (ORR). An improvement in survival or disease-related symptoms has not been established. Ibrutinib works by blocking a specific protein called Bruton's tyrosine kinase (BTK).[1] For more information, visit www.IMBRUVICA.com. The effectiveness and safety of ibrutinib alone or in combination with other treatments is being studied in several B-cell malignancies. Details about the complete ibrutinib clinical program are posted on clinicaltrials.gov.

About Siltuximab
Siltuximab is an investigational, anti Interleukin-6 (IL-6) chimeric monoclonal antibody that targets and binds to human IL-6. IL-6 is a multifunctional cytokine produced by various cells such as T cells, B cells, monocytes, fibroblasts and endothelial cells.[2] Dysregulated, or imbalanced, overproduction of IL-6 from activated B cells in affected lymph nodes has been implicated in the pathogenesis of multicentric Castleman disease (MCD), a rare blood disorder.2 Information about ongoing studies with siltuximab can be found on clinicaltrials.gov.

On September 3, 2013, Janssen announced simultaneous submissions of a Biologic License Application (BLA) to the United States Food and Drug Administration (FDA) and a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for siltuximab for the treatment of patients with MCD who are HIV-negative and HHV-8-negative. Siltuximab has been granted orphan drug status in MCD in the U.S. and EU.

About Daratumumab
In August 2012, Genmab granted Janssen Biotech, Inc. an exclusive worldwide license to develop and commercialize daratumumab. Daratumumab is an investigational human monoclonal antibody (mAb) with broad spectrum cytotoxic activity. It targets the CD38 molecule, which is highly expressed on the surface of multiple myeloma cells and may also have potential in other cancers on which CD38 is expressed. In May 2013, daratumumab was granted Breakthrough Therapy Designation by the FDA for the treatment of patients with multiple myeloma who have received at least three prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent (IMiD), or who are double refractory to a PI and IMiD.

About Janssen Research & Development, LLC
At Janssen, we are dedicated to addressing and solving some of the most important unmet medical needs of our time in oncology, immunology, neuroscience, infectious diseases and vaccines, and cardiovascular and metabolic diseases. Driven by our commitment to patients, we develop innovative products, services and healthcare solutions to help people throughout the world. Janssen Research & Development LLC and Janssen Biotech, Inc. are part of the Janssen Pharmaceutical Companies of Johnson & Johnson. Please visit http://www.janssenrnd.com for more information.

Janssen in Oncology
In oncology, our goal is to fundamentally alter the way cancer is understood, diagnosed and managed, reinforcing our commitment to the patients who inspire us. In looking to find innovative ways to address the cancer challenge, our primary efforts focus on several treatment and prevention solutions. These include a focus on hematologic malignancies, prostate cancer and lung cancer; cancer interception with the goal of developing products that interrupt the carcinogenic process; biomarkers that may help guide targeted, individualized use of our therapies; as well as safe and effective identification and treatment of early changes in the tumor microenvironment.

Additional Information about IMBRUVICA
INDICATION - IMBRUVICA is indicated for the treatment of patients with mantle cell lymphoma (MCL) who have received at least

one prior therapy. This indication is based on overall response rate. An improvement in survival or disease-related symptoms has not been established.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Hemorrhage - Five percent (5%) of patients with MCL had Grade 3 or higher bleeding events (subdural hematoma, gastrointestinal bleeding, and hematuria). Bleeding events including bruising of any grade occurred in 48% of patients with MCL treated with 560 mg daily. The mechanism for the bleeding events is not well understood. Consider the benefit-risk of ibrutinib in patients requiring antiplatelet or anticoagulant therapies and the benefit-risk of withholding ibrutinib for at least 3 to 7 days pre and post-surgery depending upon the type of surgery and the risk of bleeding.

Infections - Fatal and non-fatal infections have occurred. At least 25% of patients with MCL had infections ≥ Grade 3, according to NCI Common Terminology Criteria for Adverse Events (CTCAE). Monitor patients for fever and infections and evaluate promptly.

Myelosuppression - Treatment-emergent Grade 3 or 4 cytopenias were reported in 41% of patients. These included neutropenia (29%), thrombocytopenia (17%) and anemia (9%). Monitor complete blood counts monthly.

Renal Toxicity - Fatal and serious cases of renal failure have occurred. Treatment-emergent increases in creatinine levels up to 1.5 times the upper limit of normal occurred in 67% of patients and from 1.5 to 3 times the upper limit of normal in 9% of patients. Periodically monitor creatinine levels. Maintain hydration.

Second Primary Malignancies - Other malignancies (5%) have occurred in patients with MCL who have been treated with IMBRUVICA, including skin cancers (4%), and other carcinomas (1%).

Embryo-Fetal Toxicity - Based on findings in animals, IMBRUVICA can cause fetal harm when administered to a pregnant woman. Advise women to avoid becoming pregnant while taking IMBRUVICA. If this drug is used during pregnancy or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to a fetus.

Adverse Reactions - The most commonly occurring adverse reactions (≥ 20%) in the clinical trial were thrombocytopenia*, diarrhea (51%), neutropenia*, anemia*, fatigue (41%), musculoskeletal pain (37%), peripheral edema (35%), upper respiratory tract infection (34%), nausea (31%), bruising (30%), dyspnea (27%), constipation (25%), rash (25%), abdominal pain (24%), vomiting(23%) and decreased appetite (21%).

* Treatment-emergent decreases (all grades) of platelets (57%), neutrophils (47%) and hemoglobin (41%) were based on laboratory measurements and adverse reactions.

The most common Grade 3 or 4 non-hematological adverse reactions (≥ 5%) were: pneumonia (7%), abdominal pain (5%), atrial fibrillation, diarrhea (5%), fatigue (5%), and skin infections (5%). Treatment-emergent Grade 3 or 4 cytopenias were reported in 41% of patients.

Ten patients (9%) discontinued treatment due to adverse reactions in the trial (N=111).

The most frequent adverse reaction leading to treatment discontinuation was subdural hematoma (1.8%). Adverse reactions leading to dose reduction occurred in 14% of patients.

Drug Interactions:

CYP3A Inhibitors - Avoid concomitant administration with strong or moderate inhibitors of CYP3A. If a moderate CYP3A inhibitor must be used, reduce the IMBRUVICA dose.

CYP3A Inducers - Avoid co-administration with strong CYP3A inducers.

Special Populations - Hepatic Impairment - Avoid use in patients with baseline hepatic impairment.

For the full prescribing information, visit http://www.imbruvica.com/downloads/Prescribing_Information.pdf.

(This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995. The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Janssen Research & Development, LLC, any of the other Janssen

Pharmaceutical Companies and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to, general industry conditions and competition; economic factors, such as interest rate and currency exchange rate fluctuations; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approvals; challenges to patents; changes in behavior and spending patterns or financial distress of purchasers of health care products and services; changes to governmental laws and regulations and domestic and foreign health care reforms; trends toward health care cost containment; and increased scrutiny of the health care industry by government agencies. A further list and description of these risks, uncertainties and other factors can be found in Exhibit 99 of Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended December 30, 2012. Copies of this Form 10-K, as well as subsequent filings, are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. None of the Janssen Pharmaceutical Companies nor Johnson & Johnson undertake to update any forward-looking statements as a result of new information or future events or developments.)

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References:

[1] IMBRUVICA Prescribing Information, November 2013.

[2] El-Osta HE, Kurzrock R. Castleman's disease: from basic mechanisms to molecular therapeutics. Oncologist. 2011;16(4):497-511.