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Janssen to Present Data from its Robust Oncology Portfolio and Pipeline at the 24th EHA Annual Congress

- *Results from DARZALEX® ▼ (daratumumab) Phase 3 CASSIOPEIA study in newly diagnosed transplant eligible patients with multiple myeloma selected for the Presidential Symposium*
- *Final analysis of Phase 3 IMBRUVICA®▼ (ibrutinib) RESONATE™-2 study with five-year follow-up data in previously untreated patients with chronic lymphocytic leukaemia*

BEERSE, BELGIUM, 10 June 2019 – The Janssen Pharmaceutical Companies of Johnson & Johnson have announced the latest research to be presented at the 24th European Hematology Association (EHA) Annual Congress taking place in Amsterdam, The Netherlands, from 13–16 June 2019. Janssen will present 28 company-sponsored abstracts from its leading haematological malignancy portfolio at the congress, including the latest results for DARZALEX® (daratumumab) and IMBRUVICA® (ibrutinib).

"With more than 11,000 attendees, EHA is the premier congress for the latest innovations in haematology in Europe and Janssen is proud to be presenting important data from our clinical development programmes," said Dr Patrick Laroche, Europe, Middle East and Africa (EMEA) Haematology Therapeutic Area Lead, Janssen-Cilag France. "We are committed to changing outcomes and improving options for patients diagnosed with cancer. Therefore, we are pleased to present results from the daratumumab CASSIOPEIA study, which has been selected for inclusion in the Presidential Symposium. We are also encouraged by the five-year ibrutinib RESONATE™-2 follow-up findings, which provide longer-term evidence supporting the efficacy and safety of this BTK inhibitor in the treatment of chronic lymphocytic leukaemia."

Highlights of the data to be presented by Janssen include:

First-Time Daratumumab Data in the Treatment of Newly Diagnosed Patients with Relapsed/Refractory Multiple Myeloma, and its Investigational Subcutaneous Formulation[1,2]

Fourteen daratumumab abstracts have been selected for presentation at the EHA Annual Congress this year, four of which will be featured in oral sessions. Notably, results from the Phase 3 CASSIOPEIA study evaluating daratumumab in combination with bortezomib, thalidomide and dexamethasone for newly diagnosed patients with multiple myeloma who are transplant eligible have been selected for presentation as part of the Presidential Symposium (Abstract #S145).[1] The Presidential Symposium includes the six best abstracts of the Congress, reflecting ground-breaking research as chosen by the Scientific Program Committee. These data recently supported regulatory filings in both the European Union and the U.S., seeking to expand the current indication for daratumumab in the frontline setting.

Findings from the Phase 3 COLUMBA study will be presented (Abstract #S823) evaluating a daratumumab subcutaneous formulation in the treatment of patients with relapsed or refractory multiple myeloma.[2]

Ibrutinib Long-Term Data in Chronic Lymphocytic Leukaemia[3]

Results from the final analysis of the Phase 3 RESONATE™-2 study (PCYC-1115/1116) study evaluating ibrutinib monotherapy in previously untreated patients with chronic lymphocytic leukaemia (CLL) will be presented in an oral session (Abstract #S107).[3] Ibrutinib, a once daily oral BTK inhibitor, is jointly developed and commercialised by Janssen Biotech, Inc. and Pharmacyclics LLC, an AbbVie company.[3]

Select company-sponsored abstracts follow below. Abstracts for additional Janssen therapies will also be presented and can be found through the EHA abstract database here.

Abstract No.	**Title**	**Date/Time**
Daratumumab		
	Oral Presentations	
Abstract #S145[1]	Phase 3 Randomized Study of Daratumumab + Bortezomib/Thalidomide/Dexamethasone (D-VTd) Versus VTd in Transplant-eligible Newly Diagnosed Multiple Myeloma: Part 1 CASSIOPEIA Results	Presidential Symposium, Friday, June 14 3:45 – 4:00 PM CEST
Abstract #S874[4]	Efficacy of Daratumumab, Bortezomib, Thalidomide, and Dexamethasone in Transplant-eligible Newly Diagnosed Multiple Myeloma Based	Saturday, June 15 4:45 – 5:00 PM CEST

	Minimal Residual Disease Status: Analysis of CASSIOPEIA	
Abstract #S823[2]	Randomized, Open-label, Non-inferiority, Phase 3 Study of Subcutaneous Versus Intravenous Daratumumab Administration in Patients with Relapsed or Refractory Multiple Myeloma: COLUMBA	Saturday, June 15 11:30 – 11:45 AM CEST
Abstract #S875[5]	Subcutaneous Daratumumab, Cyclophosphamide, Bortezomib, and Dexamethasone in Patients with Newly Diagnosed Amyloid Light Chain Amyloidosis: Updated Safety Run-in Results of ANDROMEDA	Saturday, June 15 5:00 – 5:15 PM CEST
Poster Presentations		
Abstract #PF598[6]	Stem Cell Yield and Transplantation in Transplant-eligible Newly Diagnosed Multiple Myeloma Patients Receiving Daratumumab, Bortezomib, Thalidomide, and Dexamethasone: Phase 3 CASSIOPEIA Study	Friday, June 14 5:30 – 7:00 PM CEST
Abstract #PF592[7]	Impact of Age on Efficacy and Safety of Daratumumab in Combination with Lenalidomide and Dexamethasone in Patients with Transplant-ineligible Newly Diagnosed Multiple Myeloma: MAIA	Friday, June 14 5:30 – 7:00 PM CEST
Abstract #PF603[8]	Faster and Sustained Improvement in Health-related Quality of Life in Transplant-ineligible Newly Diagnosed Multiple Myeloma Patients Treated with Daratumumab, Lenalidomide, and Dexamethasone (D-Rd) Versus Rd: MAIA	Friday, June 14 5:30 – 7:00 PM CEST
Abstract #PF591[9]	Efficacy and Safety of Daratumumab, Lenalidomide, and Dexamethasone in Relapsed or Refractory Multiple Myeloma: Updated Subgroup Analysis of POLLUX Based on Cytogenetic Risk	Friday, June 14 5:30 – 7:00 PM CEST
Abstract #PF596[10]	Efficacy and Safety of Daratumumab, Bortezomib, and Dexamethasone in Relapsed or Refractory Multiple Myeloma: Updated Subgroup Analysis of CASTOR Based on Cytogenetic Risk	Friday, June 14 5:30 – 7:00 PM CEST
Abstract #PF641[11]	Characterization of Treatments and Real-life Outcomes in Patients with Newly Diagnosed Multiple Myeloma Who Received Frontline Autologous Stem Cell Transplantation in Sweden	Friday, June 14 5:30 – 7:00 PM CEST
Abstract #PF643[12]	Characterization of Frontline Treatment Patterns and the Proportion of Patients Reaching Subsequent Lines of Therapy in Transplant-eligible Patients with Newly Diagnosed Multiple Myeloma	Friday, June 14 5:30 – 7:00 PM CEST
Abstract #PS1377[13]	Improvement in Health-related Quality of Life for Newly Diagnosed Multiple Myeloma Transplant-eligible Patients Treated with Daratumumab, Bortezomib, Thalidomide, and Dexamethasone: CASSIOPEIA	Saturday, June 15 5:30 – 7:00 PM CEST
Abstract #PS1425[14]	Results of the Daratumumab Monotherapy Early Access Treatment Protocol in Patients from Europe and Russia with Relapsed or Refractory Multiple Myeloma	Saturday, June 15 5:30 – 7:00 PM CEST

Abstract #PS1395[15]	Comparative Effectiveness of Frontline Treatments for Patients with Newly Diagnosed Multiple Myeloma Who are Transplant-ineligible	Saturday, June 15 5:30 – 7:00 PM CEST
Ibrutinib		
	Oral Presentation	
Abstract #S107[3]	Five Year Follow-Up of Patients Receiving Ibrutinib For First-Line Treatment of Chronic Lymphocytic Leukemia	Friday, June 14 12:00 – 12:15 PM CEST
	Poster Presentations	
Abstract #PF384[16]	Effectiveness and Safety of Ibrutinib for Chronic Lymphocytic Leukemia (CLL) in Routine Clinical Practice: Interim Analysis (IA) of the Belgian Ibrutinib Real-World Data (BIRD) Study	Friday, June 14 5:30 – 7:00 PM CEST
Abstract #PF387[17]	French Ibrutinib Observational Study (FIRE): Real-World Study of Ibrutinib Treatment for Chronic Lymphocytic Leukemia (CLL) in France	Friday, June 14 5:30 – 7:00 PM CEST
Abstract #PF383[18]	Prognostic Testing and Treatment Approaches Based on Real-World Clinical Experience from An Interim Analysis of the INFORMCLL Registry of Patients With Chronic Lymphocytic Leukemia [ASH encore]	Friday, June 14 5:30 – 7:00 PM CEST
Abstract #PF494[19]	Clinical Outcomes with Single-Agent Ibrutinib for Relapsed/Refractory (R/R) Mantle Cell Lymphoma (MCL): Interim Analysis (IA) of the Belgian Ibrutinib Real-World Data (BIRD) Study	Friday, June 14 5:30 – 7:00 PM CEST
Abstract #PF389[20]	Progression-Free Survival Predicts Overall Survival in Frontline CLL	Friday, June 14 5:30 – 7:00 PM CEST
Abstract #PS1264[21]	French Ibrutinib Observational Study (FIRE): Real-World Study of Ibrutinib Treatment for Mantle Cell Lymphoma (MCL) in France	Saturday, June 15 5:30 – 7:00 PM CEST

#ENDS#

About daratumumab

Daratumumab is a first-in-class[22] biologic targeting CD38, a surface protein that is highly expressed across multiple myeloma cells, regardless of disease stage.[23] Daratumumab is believed to induce tumour cell death through multiple immune-mediated mechanisms of action, including complement-dependent cytotoxicity (CDC), antibody-dependent cell-mediated cytotoxicity (ADCC) and antibody-dependent cellular phagocytosis (ADCP), as well as through apoptosis, in which a series of molecular steps in a cell lead to its death.[24] A subset of myeloid-derived suppressor cells (CD38+ MDSCs), CD38+ regulatory T cells (Tregs) and CD38+ B cells (Bregs) were decreased by daratumumab.[24] Daratumumab is being evaluated in a comprehensive clinical development programme across a range of treatment settings in multiple myeloma, such as in frontline and relapsed settings.[25,26,27,28,29,30,31,32] Additional studies are ongoing or planned to assess its potential in other malignant and pre-malignant haematologic diseases in which CD38 is expressed, such as smouldering myeloma.[33,34] For more information, please see www.clinicaltrials.gov.

For further information on daratumumab, please see the Summary of Product Characteristics at https://www.ema.europa.eu/documents/product-information/darzalex-epar-product-information_en.pdf.

In August 2012, Janssen Biotech, Inc. and Genmab A/S entered a worldwide agreement, which granted Janssen an exclusive licence to develop, manufacture and commercialise daratumumab.[35]

About ibrutinib

Ibrutinib is a first-in-class Bruton's tyrosine kinase (BTK) inhibitor, which works by forming a strong covalent bond with BTK to block the transmission of cell survival signals within the malignant B-cells.[36] By blocking this BTK protein, ibrutinib decreases survival and migration of B lymphocytes, thereby delaying the progression of the cancer.[37]

Ibrutinib is currently approved in Europe for:[38]

- Chronic lymphocytic leukaemia (CLL): As a single agent for the treatment of adult patients with previously untreated CLL, and as a single agent or in combination with bendamustine and rituximab (BR) for the treatment of adult patients with CLL who have received at least one prior therapy.
- Mantle cell lymphoma (MCL): Adult patients with relapsed or refractory mantle cell lymphoma.
- Waldenström's macroglobulinemia (WM): Adult patients who have received at least one prior therapy or in first-line treatment for patients unsuitable for chemoimmunotherapy.

Ibrutinib is approved in more than 90 countries, and, to date, has been used to treat more than 140,000 patients worldwide across its approved indications.

The most common adverse reactions seen with ibrutinib include diarrhoea, neutropenia, haemorrhage (e.g. bruising), musculoskeletal pain, nausea, rash, and pyrexia.[38]

For a full list of side effects and information on dosage and administration, contraindications and other precautions when using ibrutinib please refer to the Summary of Product Characteristics for further information.

About the Janssen Pharmaceutical Companies of Johnson & Johnson

At Janssen, we're creating a future where disease is a thing of the past. We're the Pharmaceutical Companies of Johnson & Johnson, working tirelessly to make that future a reality

for patients everywhere by fighting sickness with science, improving access with ingenuity, and healing hopelessness with heart. We focus on areas of medicine where we can make the biggest difference: Cardiovascular & Metabolism, Immunology, Infectious Diseases & Vaccines, Neuroscience, Oncology, and Pulmonary Hypertension.

Learn more at www.janssen.com/emea. Follow us at www.twitter.com/janssenEMEA for our latest news. Janssen Biotech, Inc., Janssen-Cilag International NV, and Janssen-Cilag France Limited are part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding daratumumab and ibrutinib. 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 known or unknown risks or uncertainties materialise, actual results could vary materially from the expectations and projections of Janssen Research & Development, LLC., Janssen-Cilag France and any of the other Janssen Pharmaceutical Companies and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges and uncertainties inherent in product research and development, including the uncertainty of clinical success and of obtaining regulatory approvals; uncertainty of commercial success; manufacturing difficulties and delays; competition, including technological advances, new products and patents attained by competitors; challenges to patents; [product efficacy or safety concerns resulting in product recalls or regulatory action;] changes in behaviour and spending patterns of purchasers of health care products and services; changes to applicable laws and regulations, including global health care reforms; and trends toward health care cost containment. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended December 30, 2018, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in the company's most recently filed Quarterly Report on Form 10-Q, and the company's subsequent filings with the Securities and Exchange Commission. Copies of these 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 undertakes to update any forward-looking statement as a result of new information or future events or developments.

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