evaluate a relapse-free survival after discontinuation of therapy with the previous 12-months two-stage phase of TKI dose reduction. **Keywords:** chronic myeloid leukemia, tyrosine kinase inhibitor, molecular response, adverse event, clinical trial, CML

CML-277

Efficacy of Bosutinib in Imatinib-Resistant vs Dasatinib/Nilotinib-Resistant Chronic Phase Chronic Myeloid Leukemia: Results from the Phase 4 BYOND Study

B Douglas Smith [1*], Gianantonio Rosti [2], Tim Brümmendorf [3], Gail Roboz [4], Carlo Gambacorti-Passerini [5], Aude Charbonnier [6], Andrea Viqueira [7], Eric Leip [8], Frank Giles [9], Thomas Ernst [10], Frank Castagnetti [2], Andreas Hochhaus [10]

[1]Johns Hopkins Sidney Kimmel Comprehensive Cancer Center, Baltimore, MD, USA, [2]University Hospital, University of Bologna, Bologna, Italy, [3]Universitätsklinikum RWTH Aachen, Aachen, Germany, [4]Weill Cornell Medicine, New York, NY, USA, [5]University of Milano-Bicocca, Monza, Italy, [6]Institut Paoli Calmettes, Marseille, France, [7]Pfizer SLU, Madrid, Spain, [8]Pfizer Inc, Cambridge, MA, USA, [9]Developmental Therapeutics Consortium, Chicago, IL, USA, [10]Jena University Hospital, Jena, Germany

Context: Bosutinib is approved for patients with Philadelphia chromosome (Ph)+ chronic myeloid leukemia (CML) resistant/intolerant to prior therapy and newly diagnosed patients in chronic phase (CP). **Objective:** To evaluate the efficacy of bosutinib in patients with Ph+ CP CML according to subgroups of resistance (imatinib vs. dasatinib/nilotinib) or intolerance to prior tyrosine kinase inhibitors (TKIs). **Design:** BYOND (NCT02228382) is an ongoing, phase 4, single-arm, open-label study. Data are reported at ≥1 year after last enrolled patient; 85% of patients had a minimum follow-up of 2 years. **Setting:** Multicenter study in Europe and North America. **Patients:** Patients with CML resistant/intolerant to prior TKIs. **Interventions:** Bosutinib 500 mg QD (starting dose). **Main outcome measures:** Cumulative response rates. **Results:** Of 156 patients with Ph+ CP CML who received bosutinib, 52 had resistance only to imatinib, 31 had resistance to dasatinib and/or nilotinib, and 73 were intolerant to all prior TKIs. Corresponding median treatment duration was 24.1, 8.9, and 25.3 months, and median dose intensity was 360, 431, and 292 mg/day. At the data cut-off, 69.2%, 41.9%, and 53.4% of imatinib-resistant, dasatinib/nilotinib-resistant, and TKI-intolerant patients, respectively, were still receiving treatment. The main reason for discontinuation was adverse events: 19.2%, 25.8%, and 28.8% of imatinib-resistant, dasatinib/nilotinib-resistant, and TKI-intolerant patients, respectively. Corresponding discontinuations due to insufficient response occurred in 3.8%, 16.1%, and 1.4% of patients. No patient experienced on-treatment transformation to advanced phase CML. In patients without baseline complete cytogenetic response (CCyR), CCyR rates by 1 year were 65.0%, 50.0%, and 72.2% in imatinib-resistant, dasatinib/nilotinib-resistant, and TKI-intolerant patients, respectively. In patients without baseline major molecular response (MMR), cumulative MMR rates by 1 year were 55.6%, 28.6%, and 80.6% in imatinib-resistant, dasatinib/nilotinib-resistant, and TKI-intolerant patients, respectively. Deaths occurred in 3, 3, and 4 imatinib-resistant, dasatinib/nilotinib-resistant, and TKI-intolerant patients, respectively. **Conclusions:** Response rates were similar between imatinib-resistant and TKI-intolerant patients. Despite the fact that dasatinib/nilotinib-resistant patients were more heavily pretreated and had a shorter treatment duration, responses were also seen in patients with resistance to these second-generation TKIs. These results further support bosutinib use for patients with Ph+ CP CML and resistance/intolerance to prior TKIs. **Study Sponsor:** Pfizer. **Keywords:** chronic myeloid leukemia, CML, bosutinib, intolerance, resistance

CML-319

Impact of Insurance Differences in Outcomes in Colombian Patients with Chronic Myeloid Leukemia (CML)

Virginia Abello Polo [1,2,17*], Claudia Sossa Melo [3,4,17], Angela Peña [3,4,17], María Helena Solano [1,2,17], Rigoberto Gómez [5,17], Guillermo Quintero [6,7,17], Lina Abenosa [6,7,17], Henry Idrobo [6,8,17], Alicia Maria Henao Uribe [10,17], Mónica Osuna [11,17], Jheremy E Reyes [11,17], Jose D Saavedra [12,17], Juan Manuel Herrera [6,17], Isabel Munevar [13,17], Kenny M Galvez [14,17], Lina M Gaviria [15,17], Carmen Rosales O [16,17]

[1]Servicio de Hematología, Hospital de San José, Bogotá, Colombia, [2]Facultad de Medicina, Fundación Universitaria de Ciencias de la Salud, Bogotá, Colombia, [3]Servicio de Hematología y Trasplante de Progenitores Hematopoyéticos, FOSCAL, Bucaramanga, Colombia, [4]Facultad de Medicina, UNAB, Bucaramanga, Colombia, [5]HematoOncologos, Cali, Colombia, [6]Fundación Santafé de Bogotá, Bogotá, Colombia, [7]Facultad de Medicina, Universidad de los Andes, Bogotá, Colombia, [8]Centro Medico IMBANACO, Cali, Colombia, [9]Centro Médico Julián Coronel, Cali, Colombia, [10]Clinica Astorga, Medellín, Colombia, [11]Clinica los Nogales, Bogotá, Colombia, [12]Clinica VIDA, Medellín, Colombia, [13]Hematoncólogos Asociados, Bogotá, Colombia, [14]Hospital Pablo Tobón Uribe, Medellín, Colombia, [15]Hospital San Vicente de Paul, Medellín, Colombia, [16]SOHEC, Valledupar, Colombia, [17]Asociación Colombiana de Hematología y Oncología (ACHO)

Context: Adherence is a key factor for good outcomes in CML. There are two types of insurance in Colombia: Contributory (CS) and Subsidized Systems (SS), which provide highly unequal access to Tyrosine Kinase Inhibitors (TKI) for CML. **Objective:** The aim of this report is to compare outcomes in patients with different access to TKI and analyze other factors that affect progression-free survival (PFS). **Design:** The Colombian Association of Hematology and Oncology (ACHO)'s hematological disease registry (RENEHOC) is a multicenter study; it has collected information on CML patients since 2019, in 14 centers with institutional Ethics Committee approval. **Setting:** RENEHOC is a real-world registry and captures

information from academic and general community centers. **Patients or other participants:** 357 CML adult patients treated in the last 20 years. **Interventions:** Treatment was according to investigators' preferences. Imatinib was first-line treatment for 223 patients (62.4%), dasatinib for 69 (19.4%) and nilotinib 53 (14.8%); 47.9% required a second line of treatment. **Main outcome measures:** Primary end points were Optimal Response (OR) according to LeukemiaNet 2020 definition and progression-free survival (PFS) rates. The Kaplan-Meier method was used to assess PFS, and hazard ratios (HR) using Cox proportional regression modeling were estimated. **Results:** Mean age was 54 years (19–92), 60.1% were males, most patient were diagnosed in chronic phase (92%) and 36% were high Sokal. At a median follow for the entire cohort of 69 months (1–228), 60% of patients were in OR, including 11 patients in treatment-free remission (TFR). There were no significant differences between contributory and subsidized cohorts in terms of patient or disease characteristics. 76% of patients were in OP at the last visit in the CS in comparison to 48% for the SS cohort. Ten patients died, all CML-related. The only significant prognosis factors associated with PFS were Sokal score (mean PFS: 57 months low/int vs 39 high; p=0.012) and type of insurance (mean PFS 70 months for CS vs 57.7 for SS; p=0003). **Conclusions:** This report suggests that differences in access to TKI in CML according to insurance regimes results in significantly different PFS. This is the first time in the country that the impact of these attention inequalities in CML patient care have been demonstrated. **Funding:** ACHO has received grants for RENEHOC project from Takeda, Abbvie, Amgen, Dr. Reddy's. **Keywords:** chronic myeloid leukemia, CML, tyrosine kinase inhibitor, TKI, Colombia, insurance

CML-329

Allogeneic Stem Cell Transplantation Results in Chronic Myeloid Leukemia: A Single Center Experience

Andra Grigore [1,2*], Mihaela Dragomir [2], Rodica Talmaci [1,2], Zsofia Varady [2], Daniel Coriu [1,2], Ana Manuela Crisan [1,2]

[1]Carol Davila University of Medicine and Pharmacy, Bucharest, Romania, [2]Hematology and Bone Marrow Transplantation Department, Fundeni Clinical Institute, Bucharest, Romania

Context: Two decades ago, the introduction of tyrosine kinase inhibitors (TKIs) has improved the outcome and overall survival of chronic myeloid leukemia (CML) patients and changed the use of allogeneic hematopoietic stem cell transplantation (allo-HSCT) in this setting. Still, allo-HSCT remains the treatment of choice for patients diagnosed and/ or progressed to advanced phase (accelerated and blastic phase) and who have failed and/or are intolerant to multiple TKIs. **Objective:** The aim of this study was to investigate the clinical outcome in 19 patients who were referred for this procedure to The Hematology and Bone Marrow Transplantation Center, Fundeni Clinical Institute. **Design:** Retrospective single-center case series. **Setting:** The Hematology and Bone Marrow Transplantation Center, Fundeni Clinical Institute, Bucharest, Romania. **Patients:** We analyzed the records of 19 CML patients who underwent allo-HSCT between 2012–2020 in the Hematology and Bone Marrow Transplantation Center of Fundeni Clinical Institute. **Results:** Median time from CML diagnosis to allo-SCT was 34 months. Out of 19 CML patients, 6 patients were in the first chronic phase (CP), and 13 patients were in the second or later CP. TKI resistance was the most common transplant indication. Mutation status was positive in two patients. TKI intolerance was present in six patients. Out of 19 CML patients, 14 patients survived the transplantation procedure and achieved major molecular response (MMR). **Conclusions:** Allo-HSCT still represents an important therapeutic option in CML, especially for patients diagnosed or/and progressed to advanced phase or are resistant or/and intolerant to TKI treatment. **Keywords:** chronic myeloid leukemia, CML, tyrosine kinase inhibitor, TKI, allogeneic hematopoietic stem cell transplant

CML-330

Incidence of Cardiovascular (CV)-Related Hospitalizations and Associated Costs Among US Patients with Chronic-Phase Chronic Myeloid Leukemia (CP-CML) Treated with First-Line (1L) Tyrosine Kinase Inhibitors (TKI) in SIMPLICITY: An Observational Study

Stuart L Goldberg [1], Michael Mauro [2*], Jorge Cortes [3], Scott J Keating [4], Hitesh Bhandari [5], Clara Chen [4]

[1]Leukemia, Hackensack University Medical Center, Hackensack, New Jersey, United States, [2]Myeloproliferative Diseases Program, Memorial Sloan-Kettering Cancer Center, New York, New York, United States, [3]Leukemia, The University of Texas, MD Anderson Cancer Center, Houston, Texas, United States, [4]Hematology-Oncology, Bristol Myers Squibb, Princeton, New Jersey, United States, [5]SmartAnalyst India Pvt. Ltd., Gurgaon, India

Context: Evidence suggests that common CV risk factors (obesity, diabetes status, age, etc.), combined with TKI therapy, may contribute to CV events in patients with CP-CML. Furthermore, CV events occurring in patients with CP-CML are often associated with significant morbidity, mortality, and healthcare resource utilization. **Objective:** To assess the incidence of CV-related hospitalizations, subsequent length of stay (LOS), and associated costs among patients with CP-CML in a real-world setting. **Design:** Retrospective observational study. **Setting:** SIMPLICITY is an ongoing observational study of patients with CP-CML in Europe and the U.S. who are treated with 1L TKIs. Patients from the U.S. cohort were included in this analysis. **Interventions:** Dasatinib (DAS), imatinib (IM), nilotinib (NIL). **Main outcome measures:** Incidence of CV-related hospitalizations and LO, adjusted per 1000 patient-years (PY) of follow-up. Mean total hospitalization costs for each CV event were analyzed; these results will be described in the poster. **Results:** In all, 808 patients received 1L TKI therapy: IM (n=243), DAS (n=301), or NIL (n=264). Median follow-up was approximately 4 years (48.7–51.3 months). Age, treatment center type, duration of therapy, and baseline fatigue differed significantly among the groups (P<0.05). Incidence of CV-related