Arog Pharmaceuticals to Present Data at the 2020 American Society of Hematology Annual Meeting and Exposition

Dallas, Nov 5, 2020 (Issuewire.com**)** - Arog Pharmaceuticals, Inc., a Phase 3 biopharmaceutical company focused on the development of crenolanib and a related class of benzimidazole-based compounds to become treatment options for cancers with a high unmet medical need, announced that it will feature four clinical poster presentations at the 2020 American Society of Hematology (ASH) annual meeting and exposition, held virtually this year from December 5-8, 2020.

Poster Presentation, Abstract 1057

Title: Clinical Benefit of Crenolanib, with or without Salvage Chemotherapy, in Multiply Relapsed, FLT3 Mutant AML Patients After Prior Treatment with Gilteritinib

Authors: Aaron D Goldberg, MD, PhD, Mark B. Geyer, MD, Jonathan Kell, MD, Eros Di Bona, MD, Timothy S. Pardee, MD, PhD, Rupali Bhave, MD, Michael R. Grunwald, MD, Giovanni Marconi, MD, Yijia Wang, MD, MPH, Asif Pathan, PhD, RPh, and Boo Messahel, MD

Session Title: Acute Myeloid Leukemia: Novel Therapy, excluding Transplantation

Abstract Summary: Crenolanib, a type I, pan-FLT3 inhibitor, was administered on a compassionate basis to multiply relapsed FLT3-mutant AML patients after progressing on, or not responding to, gilteritinib. Patients had received 2-5 prior lines of therapy before receiving crenolanib. Six of seven (85.7%) patients demonstrated clinical benefit and five of seven (71.4%) remained on therapy as of data cutoff (18-160 days). Crenolanib plus chemotherapy led to clearance of FLT3 mutations, including the FLT3-F691 gatekeeper mutation, and active CNS Leukemia in patients while demonstrating a favorable tolerability and safety profile.

Poster Presentation, Abstract 1980

Title: Safety, Tolerability and Efficacy of Crenolanib Administered Post Allogeneic Hematopoietic Stem Cell Transplant (HSCT) in Patients with FLT3 Mutant AML

Authors: Betul Oran, MD, MS, Stefan O. Ciurea, MD, Partow Kebriaei, MD, Rohtesh S. Mehta, MD, MPH, MS, Uday R. Popat, MD, Chitra Hosing, MD, Jessica M McCarty, RN, Bridget Hindman, PhD, Boo Messahel, MD, and Richard E. Champlin, MD

Session Title: Acute Myeloid Leukemia: Biology, Cytogenetics, and Molecular Markers in Diagnosis and Prognosis

Abstract Summary: Crenolanib demonstrates favorable tolerability when administered following HSCT, with no grade 4/5 toxicities, Q/T prolongation (or other cardiac-related AE), cognitive side effects (include PRES), or differentiation syndrome. Of patients completing at least 28 days of maintenance therapy, 85% (17 of 20) remain alive and in remission with a median follow up of 35 months. Of the

three relapsing patients in this analysis, 2 relapsed after coming off-study or during a prolonged drug hold (due to GVHD) and 1 relapsed with FLT3 negative disease.

Poster Presentation, Abstract 1966

Title: Biomarker Driven Umbrella Trial of Crenolanib in Combination with Ivosidenib, Enasidenib, Venetoclax, Vyxeos and/or Salvage Chemotherapy in FLT3 Mutant AML

Authors: Naval Daver, MD, Aaron D Goldberg, MD, PhD, Courtney D. DiNardo, MD, MSc, Tapan M. Kadia, MD, Eunice S. Wang, MD, Richard M. Stone, MD, Han Zhang, MD, PhD, and Boo Messahel, MD

Session Title: Acute Myeloid Leukemia: Novel Therapy, excluding Transplantation

Abstract Summary: Planned clinical study evaluating crenolanib, a pan-FLT3 inhibitor, in combination with recently approved AML agents targeting mutations that co-occur with FLT3.Safety and clinically meaningful remission rates are the planned primary outcomes. This will be the first clinical study evaluating crenolanib in combination with venetoclax and azacytidine following demonstrated preclinical synergy.

Poster Presentation, Abstract 1973

Title: Clinical Benefit and Tolerability of Crenolanib in Children with Relapsed Acute Myeloid Leukemia Harboring Treatment Resistant FLT3 ITD and Variant FLT3 TKD Mutations Treated on Compassionate Access

Authors: Katherine Tarlock, MD, Soheil Meshinchi, MD, PhD, Jeffrey E. Rubnitz, MD, Seth E. Karol, MD, Barbara Spitzer, MD, Amit J. Sabnis, MD, Asif Pathan, PhD, RPh, and Boo Messahel, MD

Session Title: Acute Myeloid Leukemia: Novel Therapy, excluding Transplantation

Abstract Summary: Crenolanib was administered alone or in conjunction with Vyxeos in multiply relapsed/refractory children with FLT3 AML (3-9 prior therapies) as part of crenolanib's compassionate use program (five children, aged 4 – 12). Responses were observed in 80% (4/5) of pts, with two remaining alive 1 – 3.5 years after first crenolanib administration despite poor prognostic factors including multiple co-occurring mutations, complex karyotype, relapse after one or more bone marrow transplants, and multiple lines of therapy.

About Arog Pharmaceuticals, Inc.

Arog Pharmaceuticals is a US-based Phase 3 biopharmaceutical company dedicated to developing its lead investigational drug candidate, crenolanib, and a related class of benzimidazole-based compounds to become best-in-class therapies in cancer indications with high unmet medical need.

Arog was founded in 2010 to secure exclusive global rights to its product candidates from Pfizer. Since

then, Arog has enrolled over 600 patients in completed or ongoing clinical trials in acute myelogenous leukemia (AML) and advanced solid tumors.

About Crenolanib

Crenolanib, is a next-generation type I TKI that selectively and potently inhibits signaling of wild-type and mutant isoforms of class III receptor tyrosine kinases FLT3 and PDGFRα/β.

Arog is conducting pivotal, randomized Phase III trials of crenolanib designed, if successful, to secure it as a treatment option in combination with intensive chemotherapy for newly diagnosed and relapsed or refractory FLT3 AML.

For more information, please visit the company's website, **http://www.arogpharma.com**.

About FLT3 AML

FLT3 AML is an aggressive and deadly disease with limited targeted therapy options. FLT3 mutations are the most common driver mutations in AML, occurring in 25 - 33% of patients and are associated with increased rates of relapse and decreased survival.

FLT3 mutations lead to constitutive activation of the tyrosine kinase function, making FLT3 inhibition an attractive drug target in AML patients. Adding a FLT3 inhibitor to standard chemotherapy has been shown to produce longer lasting benefits compared to chemotherapy alone. Chemotherapy offers limited benefits in treating cancer cells harboring FLT3 mutations.

AML is a polyclonal disease, and multiple FLT3 mutations have been identified, including internal tandem duplications (ITD), mutations in the tyrosine kinase domain (TKD), and variant mutations. FLT3 mutations are generally regarded as poor prognostic markers in AML and a number of FLT3 mutations confer resistance to targeted inhibitors.

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