ADIENNE Pharma & Biotech presenting at 58th Annual ASH Meeting with session on Clinical Allogeneic Transplantation

Lugano, December 5, 2016; ADIENNE Pharma & Biotech SA (“ADIENNE” or “the Company” or “the Group”), an integrated biopharmaceutical group of companies based in Switzerland, announced that leading experts in the field of onco-hematology and bone marrow transplantation today have presented a poster and an oral presentation highlighting Phase I and Phase II data on ADIENNE’s lead compound Begelomab at the American Society of Hematology (ASH) Annual Meeting, which is taking place in San Diego, USA, from December 3-6, 2016:

- Title: Treatment of Patients with Steroid Refractory Acute Graft Vs Host Disease (SR-GvHD): A Matched Paired Analysis of Anti-CD26 (Begelomab) Compared to Other Treatment

The clinical data presented today conclude that Begelomab induces a high remission rate on day+28, in patients with steroid refractory acute GvHD, including a proportion of severe gut and liver GvHD. Non relapse mortality at 6 months was significantly lower in Begelomab treated patients, as compared to a group of 82 matched controls. This finding has been observed despite a significantly greater proportion of patients with liver stage 3-4 GvHD in the Begelomab group. Furthermore, a borderline survival advantage at 1 year for Begelomab patients has been observed.

To confirm these results, a multicenter prospective randomized registrative trial for the treatment of patients with SR-aGvHD in the United States and several European countries is currently ongoing. This trial, comparing Begelomab versus best available (off-label) therapies, will involve more than 30 clinical centres with approximately 200 patients enrolled. Today, Begelomab trial is the only registrative trial currently ongoing in patients with SR-aGvHD. For further information, please visit https://clinicaltrials.gov/ct2/show/NCT02411084.

“In addition to the excellent safety data, Begelomab has also shown significant results in terms of clinical activity in GvHD. With these promising clinical results, we are making an important step towards our vision to help patients to survive this deadly disease”, commented Dr. Antonio Francesco Di Naro, Chairman and President of ADIENNE.

The abstract will also be published online in the December supplemental volume of “Blood”.

With more than 16,000 members from nearly 100 countries, the American Society of Hematology (ASH) is the world’s largest professional society serving both clinicians and scientists around the world who are working to conquer blood diseases.

About Begelomab

Begelomab is ADIENNE’s lead clinical product candidate that is currently undergoing a registrative Phase II/III clinical trial in steroid-resistant acute Graft-versus-Host Disease. In parallel, ADIENNE plans to achieve a label extension of Begelomab as a second line therapy in SAA where standard immunosuppressive agents have failed. SAA results from a reduction in the number of multipotent stem cells combined with an inability of existing cells to repopulate bone marrow.
Begelomab has been granted ODD for the treatment of GvHD in the U.S., E.U. and Switzerland. Currently, Begelomab is provided via compassionate use program in clinical centres in Europe that make a specific request and are not participating in the Phase II/III clinical trial.

About ADIENNE

ADIENNE is an integrated biopharmaceutical group of companies based in Lugano, Switzerland, with a proprietary portfolio of orphan-designated marketed medicinal product, clinical and preclinical product candidates. ADIENNE is focused on orphan drug development for the treatment of various hematological and immunological diseases. In addition, the Group has its own Good Manufacturing Practice ("GMP")-approved manufacturing facility, which is authorized for the production of biotechnological sterile products for clinical trials and commercial use. More on www.adienne.com.

For further details, please contact

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