ADIENNE Pharma & Biotech relaziona al 58° Annual ASH Meeting in una sessione dedicata al Trapianto Allogenico

Lugano, 5 dicembre 2016; ADIENNE Pharma & Biotech SA (“ADIENNE” o “la Società” o “il Gruppo”), gruppo biofarmaceutico integrato con sede in Svizzera, annuncia che i maggiori esperti al mondo di oncoematologia e di trapianto di midollo hanno presentato in data odierna, in occasione dell’American Society of Hematology (ASH) Annual Meeting in corso a San Diego, USA, dal 3 al 6 dicembre 2016, sia in un poster che in una presentazione orale, i dati degli studi di Fase I e Fase II relativi a Begelomab, principale prodotto in sviluppo di ADIENNE:

- Titolo: 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

I dati presentati dimostrano come Begelomab induca un significativo tasso di remissione al giorno +28 in pazienti affetti da GvHD acuta steroide-resistente, compresi quella percentuale di pazienti con GvHD epatica e del tratto intestinale. La mortalità non da recidiva a 6 mesi è risultata significativamente inferiore nei pazienti trattati con Begelomab rispetto agli 82 pazienti del gruppo di controllo, nonostante nel gruppo di Begelomab fosse presente una percentuale maggiore di pazienti affetti da GvHD epatica di grado 3-4. Inoltre, l’indice di sopravvivenza a 1 anno è risultato più elevato nel gruppo di pazienti trattati con Begelomab.


“Oltre agli eccellenti dati di sicurezza, Begelomab ha dimostrato importanti risultati in termini di efficacia clinica nella GvHD. Tali risultati rappresentano un importante passo avanti verso quello che è il nostro obiettivo, ovvero favorire la sopravvivenza dei pazienti affetti da questa patologia letale”, ha commentato il Dr. Antonio Francesco Di Naro, Chairman e Presidente di ADIENNE.

L’abstract sarà pubblicato online all’interno del supplemento al numero di dicembre della rivista “Blood”.

1
Con più di 16.000 membri di quasi 100 Paesi, l’American Society of Hematology (ASH) rappresenta la più grande associazione di medici specialisti e scienziati attivi nel settore delle patologie ematologiche.

**Begelomab**

Begelomab è il principale prodotto candidato di ADIENNE ed è in studio clinico registrativo di Fase II/III per il trattamento della malattia acuta del trapianto contro l’ospite steroide resistente (aGraft-versus-Host Disease steroid-resistant). Parallelamente, ADIENNE prevede di ottenere un’estensione d’uso di Begelomab come terapia di seconda linea in SAA, dove gli agenti immunosoppressori si sono rivelati inefficaci. La SAA deriva da una riduzione del numero di cellule staminali multipotenti associata all’incapacità da parte delle cellule esistenti di ripopolare il midollo osseo.

Begelomab ha ottenuto la designazione di Farmaco Orfano per il trattamento della GvHD negli Stati Uniti, in Europa e in Svizzera. Attualmente Begelomab viene fornito attraverso un programma di uso compassionevole ai centri clinici europei che ne fanno specifica richiesta e che non partecipano allo studio clinico di Fase II/III.

**ADIENNE in breve**

ADIENNE è un gruppo biofarmaceutico integrato con sede a Lugano, Svizzera, che detiene un portfolio costituito da un farmaco orfano registrato in commercio e da prodotti candidati in fase clinica e preclinica. ADIENNE focalizza la propria attività sullo sviluppo di farmaci orfani per il trattamento di varie patologie ematologiche e immunologiche. Il Gruppo dispone inoltre di un proprio sito produttivo approvato GMP (Good Manufacturing Practice, buone pratiche di fabbricazione), autorizzato alla produzione di prodotti biotecnologici sterili per sperimentazioni cliniche ed a scopo commerciale. Maggiori informazioni sul sito www.adienne.com.

**Per ulteriori dettagli:**

<table>
<thead>
<tr>
<th>Investitori</th>
<th>Media</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr. Antonio Francesco Di Naro Chairman e Presidente</td>
<td>Martin Meier-Pfister Ufficio Stampa</td>
</tr>
<tr>
<td>Tel.: +41 91 210 47 26 E-Mail : <a href="mailto:ir@adienne.com">ir@adienne.com</a></td>
<td>Tel.: +41 43 244 81 40 E-Mail: <a href="mailto:adienne@irfcom.ch">adienne@irfcom.ch</a></td>
</tr>
</tbody>
</table>

This press release and any information, whether or not in writing, supplied in connection therewith are private and strictly confidential and are being shown to you solely for your information purposes and are not research. The information may not be reproduced, distributed to any other person or published, in whole or in part, for any purpose.

This press release has been prepared by ADIENNE Pharma & Biotech SA (the “Company”, and together with ADIENNE S.r.l., ADIENNE SA and their respective subsidiaries, the “Group”) and comprises the slides for a press release to institutional investors concerning the Company, its proposed listing on the SIX Swiss Exchange and the proposed offering of its ordinary shares.

The information contained in this press release has not been independently verified. This press release does not purport to be all-inclusive or to contain all the information that a prospective purchaser of securities of the Company may desire or require in deciding whether or not to offer to purchase such securities. This press release does not constitute or form part of any offer to sell or issue, or invitation to purchase or subscribe for, or any solicitation of any offer to purchase or subscribe for, any securities of the Company, nor shall it or any part of it nor the fact of its distribution form the basis of, or be relied on in connection with, any contract or investment decision.
This press release is not an offering circular within the meaning of Article 652a of the Swiss Code of Obligations, nor is it a listing prospectus within the meaning of the listing rules of the SIX Swiss Exchange or a prospectus under any other applicable laws. Investors should not subscribe for or purchase any shares of the Company referred to in this press release except on the basis of information in any prospectus (and any supplement(s) thereto) if and when published by the Company. Copies of any prospectus will, following publication, be available from the Company's registered office. This document does not constitute a recommendation regarding the shares of the Company. Any decision to purchase ordinary shares of the Company should be made solely on the basis of information to be contained in an offering circular if and when published by the Company. No reliance may be placed for any purpose whatsoever on the information contained in this press release, or any other material discussed verbally, or on its completeness, accuracy or fairness. This press release should not be considered as a recommendation by the Company, any selling shareholders or any of their respective advisers and/or agents that any person should subscribe for or purchase any securities of the Company. Prospective purchasers of securities of the Company are required to make their own independent investigation and appraisal. Any prospective purchaser of the shares in the Company is recommended to seek its own independent financial advice.

Neither this document nor any part or copy of it may be taken or transmitted into the United States of America ("United States") or distributed, directly or indirectly, in the United States. This press release is not directed at persons located in the United States other than "qualified institutional buyers" as defined in Rule 144A under the U.S. Securities Act of 1933 (the "Securities Act"). The Company's securities have not been and will not be registered under the U.S. Securities Act of 1933 (the "Securities Act") or the securities laws of any state in the United States and may not be offered or sold in the United States except in reliance on an exemption from, or in a transaction not subject to, the registration requirements of the Securities Act. Any public offering of securities in the United States requires the publication of a prospectus by the issuer of such securities containing detailed information about the Company and its management, as well as the Company's financial statements.

This press release is only addressed to and is only directed at persons in member states of the European Economic Area (the "EEA") who are "qualified investors" within the meaning of Article 2(1)(e) of the Prospectus Directive (Directive 2003/71/EC and amendments thereto, including Directive 2010/73/EU, to the extent implemented in the relevant member state of the EEA) and any implementing measure in each relevant member state of the EEA ("Qualified Investors"). In the United Kingdom, this press release is only directed to those persons who (i) have professional experience in matters relating to investments who fall within the definition of "investment professionals" in Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended (the "FPO") or (ii) fall within Article 49(2)(a) to (d) of the FPO (all such persons being together referred to as " Relevant Persons"). This press release must not be acted on or relied upon (a) in the United Kingdom, by persons who are not Relevant Persons, and (b) in any member state of the EEA, by persons who are not Qualified Investors. Any investment or investment activity to which this press release relates is available only to (i) in the United Kingdom, Relevant Persons and (ii) in any member state of the EEA other than the United Kingdom, Qualified Investors, and will be engaged in only with such persons. Requests resulting from this press release will only be responded to if the person concerned is, (i) in the United Kingdom, a Relevant Person, and (ii) in any member state of the EEA other than the United Kingdom, a Qualified Investor. The information contained in this press release is not intended to lead to the conclusion of any contract of whatsoever nature.

Neither this document nor any part or copy of it may be taken or transmitted into Australia, Canada or Japan, or distributed directly or indirectly in Canada or distributed or redistributed in Japan or to any resident thereof. Any failure to comply with the above restrictions may constitute a violation of U.S., Australian, Canadian or Japanese securities laws. Copies of this press release may not be sent to countries in which this is barred or prohibited by law. The distribution of this document in other jurisdictions may be restricted by law, and persons into whose possession this document comes should inform themselves about, and observe, any such restrictions.

No repress release or warranty, express or implied, is made or given by or on behalf of the Group Jefferies International Limited or any of their respective affiliates (within the meaning of Rule 405 under the Securities Act) ("Affiliates"), members, directors, officers or employees or any other person as to the accuracy, completeness or fairness of the information or opinions contained in this press release or any other material discussed verbally. None of the Company, Jefferies International Limited or any of their respective Affiliates, members, directors, officers or employees accepts any liability whatsoever for any loss howsoever arising from any use of this press release or its contents or otherwise arising in connection therewith.

The information in this press release includes forward-looking statements which are based on current expectations and projections about future events. These forward-looking statements, as well as those included in any other material discussed at any roadshow press release, are subject to risks, uncertainties and assumptions about the Company and its subsidiaries. The inclusion of forward-looking statements should not be regarded as a repress release by the Company of what the Company will actually achieve in the future. Actual results may differ materially from the planned results set forth in this document due to the risks and uncertainties inherent in the Company's ability to develop and expand its business, obtain various approvals from regulatory authorities, successfully complete development of its current product candidates and current and future collaborations for the development and commercialisation of its product candidates, assess the future development of orphan drug markets and the markets for the Company’s products and forecast its future revenues, capital expenditures and financial resources. In light of these risks, uncertainties and assumptions, the events in the forward-looking statements may not occur. No repress release or warranty is made that any forward-looking statement will come to pass. No one undertakes to publicly update or revise any such forward-looking statement, whether as a result of new information, future events or otherwise. Neither the Company nor any of its Affiliates or their respective bodies, executives, employees or advisers assume any responsibility to up-date forward-looking statements or to adapt them to future events or developments. The information and opinions contained in this press release are provided as at the date of this press release and are subject to verification, completion and change without notice.
In giving this press release, neither the Company nor its advisers and/or agents undertake any obligation to provide the recipient with access to any additional information or to update this press release or any additional information or to correct any inaccuracies in any such information which may become apparent, or to publicly announce the result of any revision to the statements made herein except to the extent they would be required to do so under applicable law or regulation. By attending the press release you agree to be bound by the foregoing limitations.