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NDA Group Releases Data Comparing FDA and EMA Ahead of Annual DIA EuroMeeting in Hamburg

In spite of similar approval numbers, the US continue to outpace Europe
Oncology is most active therapeutic area

Hamburg, Germany (April 5, 2016) – NDA Group announced today their findings from its third annual comparison of drug approvals in the United States and Europe, in preparation for this year’s DIA EuroMeeting in Hamburg. This year’s Status of New Drug Approvals report serves to emphasize the need for a streamlined global development and commercialization process across the world’s two biggest markets.

This year’s report – based on preliminary research figures distilled from the FDA and EMA websites on January 26, 2016 – found that FDA and EMA were equally productive in 2015, with a total of 89 new approvals granted. However, while 34 of those approvals came from the US and 32 in the EU, 24 drugs approved in the EU in 2015 had received prior approval in the US, while only 10 products out of 34 registered in the US in 2015 were previously approved in the EU.

“Understanding the needs and requirements of regional or even local stakeholders has become critical for biopharmaceutical companies looking to achieve a product’s full market potential,” said Johan Strömquist, CEO, NDA Group. “Integrating these requirements and developing strategies and plans to successfully meet them is at the heart of what we do at NDA. The differences between the two regions are natural given history, procedures and available regulatory pathways. The gap is however unnecessary and by bridging it companies would get the benefits of market presence in the world’s two largest markets. Critically, addressing this would provide patients on both continents access to important medical therapies faster.”

Last month, NDA Group, a leading strategic regulatory and HTA consultancy in Europe announced its merger with PharmApprove, a leading strategic regulatory and scientific communications consultancy in the US.

Olga Björklund, PhD, NDA’s Senior Consultant behind the research commented: “The findings released today indicate that drug development companies generally prefer to apply for approval in the US before pursuing the EU. Additionally, the FDA has a higher rate of granting special approval status through priority review designation, accelerated approval, fast track designation, and expedited approval. It is expected that with the EMA’s initiatives, such as early interactions between regulatory and health technology assessment bodies, interactions with committee for advanced therapies and the recent launch of the scheme for priority medicines (PRIME) there will be a noticeable impact on the approval statistics in Europe.”

Of all new products that received marketing approval in 2015, 41.6% (37/89) underwent special approval procedures, with FDA granting 27 and EU 13, which is a small increase compared to 2014, but almost double the number from 2013 in both regions.
As for therapeutic areas, the busiest was oncology, with 23.6% (23/89) of the marketing authorizations granted during 2015. Approvals in infections dropped to second place, from 23.3% in 2014 to 14.6% for 2015. Those were followed by the products for endocrine system (12/89), cardiovascular (9/89) and respiratory system (9/89). Filgrastrim Sandoz was the only biosimilar to be approved in the US in 2015 (approved in the EU in 2009). In the EU no new approvals for biosimilars were granted in 2015, though 3 gained approval in 2014.

NDA’s CEO, Johan Strömquist as well as the company’s Scientific Director, Dr. Markku Toivonen and the Director of NDA’s Advisory Board, Prof. Steffen Thirstrup together with a line-up of experts, will be present at DIA EuroMeeting and available to discuss these findings, as well as the global implications of NDA’s merger with PharmApprove. **NDA staff can be found in stand A 2, 3 of Congress Center**, and in the following presentations:

- **Shelley Gandhi & Bill Richardson** pre-conference tutorials Tutorial 2 | Wednesday, 06 April, 09:00-12:30  
  *Moving from Risk Management to Benefit/ Risk Management - Embedding Pharmacovigilance Principles into the product life cycle*

- **Shelley Gandhi** Session 1402 | Thursday 7th April - 11:00 -12:30  
  *Communicating Benefit risk information in risk management plans to medical professionals and the general public - Benefit Risk communication in the life cycle & how it is reflected in PSURs and RMPs*
• Dr. Gopalan Narayanan  Session 0201 | Thursday 7th April 09:00-10.30  
  *Translation of Cell & Gene Therapies*

  Session 0903 | Thursday 7th April, 14:00-15:30
  *Advanced Therapies: Planning the Long Term Follow up?*

• Professor Steffen Thirstrup Session 1302 | Thursday, 07 April, 11:00-12:30
  *How will Payers React to the Future of Drug Development?*

  Session 0405 | Friday 8th April 09:00-10:30
  *Regulatory Strategies for Early Dialogue: Scientific Advice including joint EMA/HTA and National Advice and Pilot Scientific Advice on PASS*

• Dr. Simon Day Session 0106 | Friday, 08 April, 11:00 – 12:30
  *Standards of Evidence – From Blockbusters to Orphans*

• Professor Beatriz Silva Lima Session 0406 | Friday, 8th April - 11:00 -12:30
  *Evolving Areas of Regulatory Science*

To learn more about NDA’s recent merger with US-based PharmApprove, visit ndareg.com/pharmapprove or contact info@ndareg.com (EU) or info@pharmapprove.com (US). For more about NDA’s involvement with the 2016 DIA EuroMeeting, visit ndareg.com/meet-nda-at-the-dia-euromeeting-2016/. And to explore the full Status of New Drug Approvals for 2015 report, visit ndareg.com/europe-vs-usa-new-drug-product-approvals-in-2015/.

**About NDA**
NDA Group is a leading global drug development consultancy providing small as well as large, multi-national pharmaceutical companies with strategic advice and operational support to get good medicines to market and keep them there. Based in Boston, London, Munich, New Jersey, Stockholm and Zurich, NDA offers a range of professional drug development consulting services that spans from early development phase to lifecycle management of a medicinal product. These services incorporate regulatory affairs, health technology assessment, pharmacovigilance and quality assurance. Clients are supported by a team of over 100 consultants and a unique Advisory Board comprising industry experts, many of whom are ex-European Agency and FDA staff. For more information, visit ndareg.com.

**About PharmApprove**
PharmApprove is the leading strategic, regulatory, and scientific communications consultancy to the pharmaceutical and biotech industries. The firm offers both strategic and tactical support to companies facing high-profile, high stakes events and engagements anywhere along the road to approval and commercialization – including FDA Advisory Committee meetings. PharmApprove helps clients win health authority approvals, deliver compelling regulatory communications, and make persuasive pharmacoeconomic arguments to payers and HTAs. Learn more at pharmapprove.com and follow them socially at twitter.com/pharmapprove and facebook.com/pharmapprove.

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