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

Drop in US drug approvals but no similar trend is seen in EU

Glasgow, United Kingdom (March 28, 2017) – NDA Group announced findings from their fourth annual comparison of drug approvals in Europe and the United States, ahead of this year's DIA EuroMeeting in Glasgow. This year's Status of New Drug Approvals report emphasises the need for a streamlined global development and commercialisation process across the world's two biggest markets.

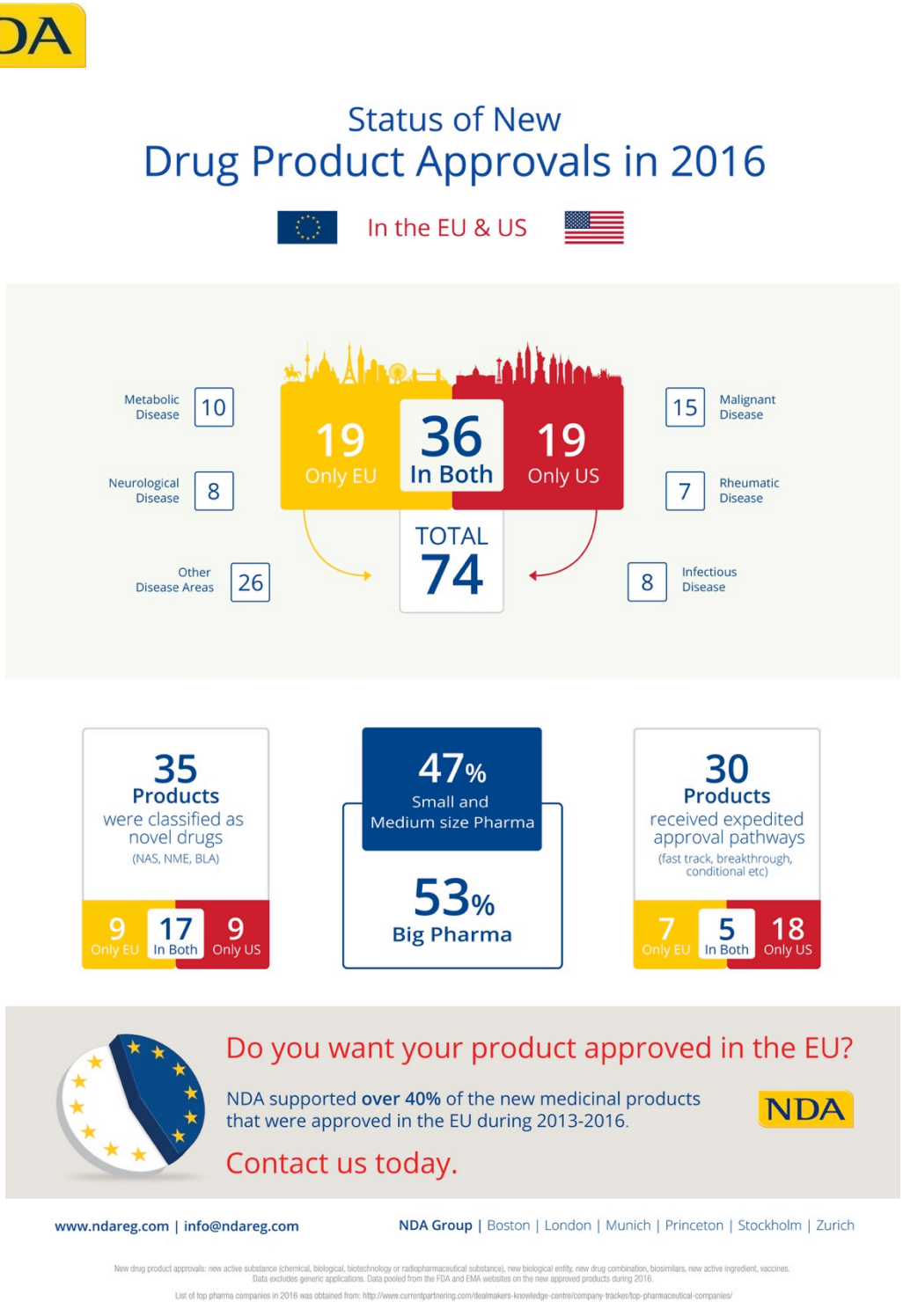
The report – based on preliminary research figures from the EMA and FDA websites in January 2017 – found that there has been a drop in US approvals but not in EU. For 2016 there were 74 new drug approvals granted in the US and EU. Of these new products, 19 were approved only in the EU, 19 only in the US, and 36 were granted in both regions. However 17 drugs that were approved in the EU in 2016 had received prior approval in 2015 or earlier in the US, while only six products registered in the US in 2016 were previously approved in the EU.

Johan Strömquist, CEO, NDA Group "Understanding the evolving regulatory landscape and requirements is a key concern for the drug developing industry, as is it for us at NDA. It is intriguing to see how expedited pathways shape this year's statistics just like it did last year, but with a very different outcome. It's also interesting to see the continued rise of smaller companies in the percentage of products taken to market."

"Our analysis for 2016 shows that NDA maintains an exceptional position in supporting new drug product approvals in Europe. During the last four years NDA supported over 40% of the new drugs approved with a broad range of services. I'm also excited to see the increase of products going through the FDA that received NDA's support. NDA supported over 20% of new drugs that achieved approval by the FDA during 2016."

Terese Johansson, PhD, NDA's consultant behind the research commented: "The findings show that FDA has had a significant drop in drug approvals but continues to grant more expedited and nonstandard review approval status than the EMA. The drop is not as pronounced in the EU but is likely to be more prominent in 2017. Expedited drug development and nonstandard review approval pathways are the new norm in the US, but in the EU special approval procedures are not as common. The US situation could be explained by the increased use of the shorter nonstandard approval pathways since there has also been a significant increase in complete response letter (CRL). During 2016 FDA issued 14 CRLs, compared to just two in 2015."

"The report also highlights the continued trend that many companies first seek approval in the US. Both the EU and US show increases in drug approvals from small and medium sized pharma but big pharma still dominates the drug approval statistics. The busiest therapeutic area was oncology."



The pooled statistics showed that of the new drug approvals, 35 were classified as novel drugs (e.g. NAS, NME or BLA), nine were approved only in the EU, nine only in the US and 17 in both regions. For the EMA, the number represents the fewest NASs approved since 2011, while the FDA has not approved this few NMEs/BLAs since 2010. Big pharma represented 53% of the new drug approvals in 2016 vs 47% from small and medium sized pharma. For big pharma this is a decrease compared to previous years. Of all new products that received marketing approval in 2016, 30 products underwent special approval procedures like Conditional, Fast Track, Breakthrough, Accelerated Approval and Priority Review, 18 in the US, seven in EU and five in. In many cases more than one of these pathways was granted per product.

NDA Strategic Advisor and former Chief Exec of the EMA, **Dr. Thomas Lönngren**, as well as the company's Scientific Director, **Dr. Markku Toivonen** and the Director of NDA's Regulatory Advisory Board, **Prof. Steffen Thirstrup** will be present at DIA EuroMeeting together with a line-up of experts, and available to discuss these findings.

NDA staff can be found at booth C 10, 11 of the Congress Center and in the following presentations:

- **Shelley Gandhi & Bill Richardson** - Ex MHRA Regulators
  (Pre-Conference Short Course) Short Course 4 | Wed, 29th March - 09:00-12:30
  Moving from Risk Management to Benefit / Risk Management - Embedding Pharmacovigilance Principles into the product life cycle

- **Dr Mira Pavlovic** - HTA Expert, Session Chair
  Session 0101 | Wed, 29th March - 16:30-18:00
  Global dossier for clinical development

- **Prof. Steffen Thirstrup** – Director NDA Regulatory Advisory Board – Session Chair
  Session 0302 | Thurs, 30th March - 11:00-12:30
  EU clinical trial regulation and its implications

- **Prof. Beatriz Silva Lima** - Non clinical Expert
  Session 1002 | Thurs, 30th March - 11:00-12:30
  Optimising the development of paediatric medicines

- **Dr Markku Toivonen** - Scientific Director & Medical Advisor - Session Chair
  Paul Chamberlain - Biopharmaceutical Development & Immunology Specialist - Session Speaker
  Session 0303 | Thurs, 30th March - 14:00-15:30
  Immunogenicity assessment-risked-based approaches

For more about NDA's involvement with the 2017 DIA EuroMeeting, visit http://www.ndareg.com/meet-nda-at-the-dia-euromeeting-2017/.

To explore the full Status of New Drug Approvals for 2016 report, visit http://www.ndareg.com/europe-vs-usa-new-drug-product-approvals-in-2016/.

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 span Development Strategy, Translational Science, Procedure & Submission Management, High-Stakes Meetings and Process Design & Optimisation. Clients are supported by a team of over 150 regulatory affairs, health technology assessment, pharmacovigilance, quality assurance and strategic communications professionals. Backing all major NDA projects is the unique NDA Advisory Board comprising industry experts, many of whom are ex- European Agency and FDA staff. Learn more at www.ndareg.com and follow them at www.linkedin.com/company/nda-group-ab.

About PharmApprove
The NDA PharmApprove team comprises leading strategic, regulatory, and scientific communications professionals. PharmApprove focuses on 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 http://www.pharmapprove.com/ and follow them socially at twitter.com/pharmapprove.

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