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NDA Group and PharmApprove Announce Merger

European and US-based companies combine to create the world's leading drug development consultancy

Princeton, NJ and Stockholm, Sweden (March 22, 2016) – NDA Group, a leading strategic regulatory and HTA consultancy in Europe, and PharmApprove, a leading strategic regulatory and scientific communications consultancy in the US, announced their merger today. The newly combined company will allow clients to streamline the global development and commercialization process, accelerating patient access to important medical therapies. Through the merger, NDA and PharmApprove will offer clients an unparalleled breadth of global experience and expertise to drive efficient product development across the US and Europe.

"NDA has supported over 45% of new medicinal products that were approved in Europe over the past three years, and more than half from the last year," said Johan Strömquist, CEO of NDA Group. "By working together, NDA and PharmApprove offer clients a single partner that can provide a clear development path – considering both regulatory and market access requirements – to offer streamlined, strategic drug development advice across the world's two largest markets."

"With a high success rate of supporting clients preparing for FDA Advisory Committees and other regulatory milestones, PharmApprove has a long track record of great results," said Laurie Smaldone Alsup MD, President of PharmApprove. "We will continue to provide comprehensive advisory committee services and expand our global support. Our culture is a perfect complement to NDA Group; we both believe in engaging highly experienced and high-quality people who provide expert guidance to our clients."

The combined companies offer more than 35 years of experience in the drug development space, and boast a network of over 1,000 experts across a range of technologies, disciplines and therapeutic areas. NDA and PharmApprove will each retain their current staff and leadership, including more than 150 consultants, while adding to their capabilities and transatlantic reach.

"The deep knowledge of regulatory agencies and their requirements that I and my fellow NDA and PharmApprove consultants can provide is essential for any company looking to bring important new treatments to patients in need," said NDA Group's Strategic Advisor, and former head of the European Medicines Agency, Dr. Thomas Lönngren. "With our involvement in every step of the drug development process, we can prevent costly missteps – and ultimately ensure that clients have the best chance to prove the safety and efficacy of their drugs worldwide."

The merger comes after nearly a year of strategic alliance between the two top firms.

"My experience working with NDA and PharmApprove clearly demonstrated that this is a case where the whole **is** greater than the sum of its parts," explained Dr. Ron Robison, Vice President, Global Regulatory Affairs, Pharmacovigilance and R&D QA for AbbVie. "Having seamless, simultaneous access to regulatory experts in multiple markets helped us to develop the strategies we need to support optimal labeling and market access opportunities."

PharmApprove was created in 1999 by New Jersey-based Taft and Partners. Pete Taft, founder and CEO of PharmApprove, will no longer have an executive role, but will continue to serve as a consultant to the combined company.

To learn more about the integrated global expertise this merger represents, visit www.ndareg.com/pharmapprove or contact info@ndareg.com (EU) or info@pharmapprove.com (US).

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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