



Diamond Pharma Services wins both Futures and Support categories at TOPRA Awards

Double-win recognises Diamond's role supporting Kite Pharma Inc in the development of its breakthrough CAR-T cell cancer therapy

Harlow, Essex, UK, 02 November 2018 – Diamond Pharma Services Ltd (“Diamond”), a leading technical services and regulatory affairs consulting group, providing expert support and advice to pharmaceutical and biotechnology companies, has received both the Futures and Support Award at The Organisation for Professionals in Regulatory Affairs (TOPRA) Awards. The Awards recognise the role of the Company’s expert regulatory services in supporting Kite Pharma Inc’s successful development of its CAR-T cell immunotherapy product for lymphoma and leukaemia.

Established in 2010, the TOPRA Awards recognise the achievement of individuals, teams and organisations in the regulatory affairs community. The Futures Award acknowledges the role of regulatory scientists in realising the potential of cutting-edge technologies and the Support Award recognises the critical role supporting organisations play in the drug development process and lifecycle of a drug. Diamond won both categories for its services to Kite Pharma Inc; supporting the successful development of its breakthrough CAR-T cell immunotherapy product, YESCARTA® through to Marketing Authorization Application (MAA). Diamond has been previously recognised by TOPRA with the Innovation Award (2012) and Futures Award (2015) for playing an integral part in the European regulatory approval of the first gene therapy product, Glybera, and subsequently paving the way for existing regulatory framework for such products.

Diamond provides high quality strategic and operational services to the pharmaceutical and biotechnology industry. The regulatory team supported Kite Pharma Inc in all European regulatory activities, including engagement with regulatory authorities, dossier writing, scientific advice meetings, orphan designations for six conditions, ATMP classifications, paediatric investigation plans, clinical trial applications, GMO applications, and the coordination and leadership for Marketing Authorisation applications across several EU countries. The complexity of cell and gene therapy development through to market is particularly challenging due to regulatory framework, the novelty of products, the unusual mechanism of action, and due to typically rare disease indications.

Maureen Graham, Managing Director, Regulatory, Diamond Pharma Services, said: *“Diamond is dedicated to supporting innovative companies, such as Kite Pharma, in the development of life-changing products and to bring new therapies to commercialisation for the benefit of patients. To have won both the Futures and Support TOPRA Awards for our work on this project is an absolute honour. The awards recognise the strength of the Diamond Pharma Services team, and we are extremely proud of our work to address a world-wide unmet medical need.”*

For further information about Diamond Pharma Services visit <https://www.diamondpharmaservices.com/>

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Notes to Editors

About Diamond Pharma Services <https://www.diamondpharmaservices.com/>

Diamond Pharma Services Limited ("Diamond") is a regulatory affairs and product development consultancy headquartered in the UK, with offices in Europe as well as a US subsidiary.

Diamond's skilled team of qualified regulatory professionals has many years' experience in regulatory, pharmacovigilance, compliance and quality, and pharmaceutical/biologics technical development

Diamond provides support from early stage development through to life cycle management of approved products, across all therapeutic areas, medicinal products, and devices, including small molecule and next generation biologics, through to cell and gene therapy products.

Diamond has been twice recognised by TOPRA (The Organisation for Professionals in Regulatory Affairs), for excellence and innovation in EU regulatory affairs.