PROVIDING PRE-LAUNCH ACCESS

CLINIGEN

SITUATION

small Pharmaceutical company

NEUROBLASTOMA

A small Pharmaceutical company acquired the rights to a medicine in development for Neuroblastoma. Their main objective was to file for approval and then commercialize first in Europe followed by other territories. However, there was a high demand for pre-launch access in Europe and other markets globally that needed to be responded to quickly given the unmet medical need. There was also a competitive product in development so it was important for a fast, reliable response and turn around for all eligible requests for Early Access to give Health Care Providers (HCPs) the best possible experience using this new medicine.

high demand

fast, reliable response

OBJECTIVES

- Ensure access was only provided to eligible patients and that HCPs were given appropriate support to ensure a positive experience
- Ensure all requests were dealt with quickly and efficiently no matter where they came from globally
- Implement a sustainable and self funding program that could be continued for many years in late to launch or countries where launch would never occur
- Partner with a company that had the same sense of urgency and patient focus

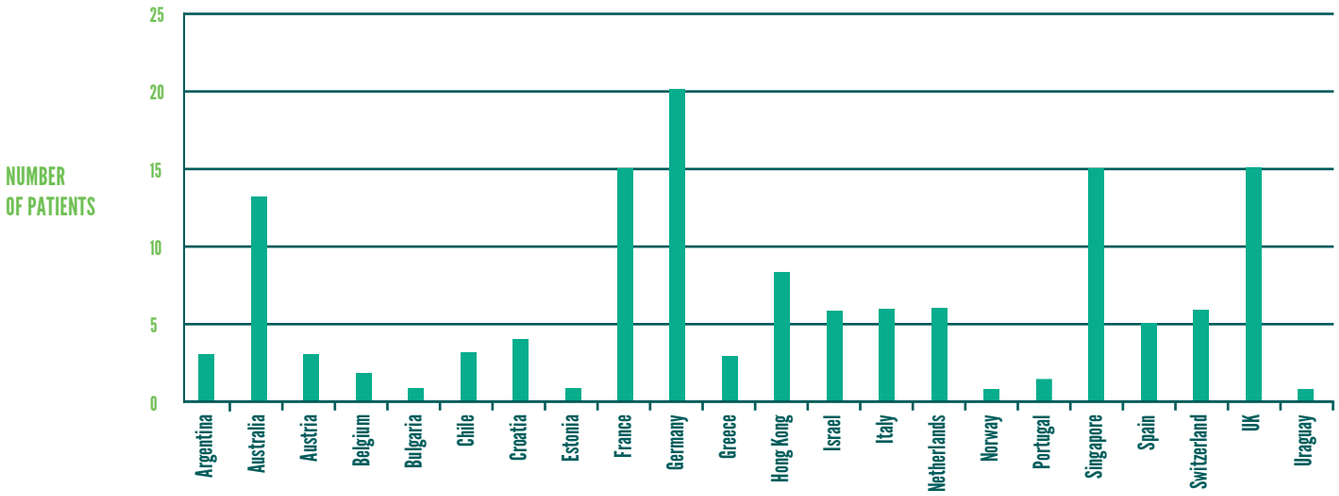
CLINIGEN SOLUTION

- Screened all patients against **pre-defined eligibility criteria** to ensure access was provided to the right patients
- Provided regulatory and medical guidance to HCPs to ensure a smooth process for access and a positive access experience
- **Charged for access** and collected payment from sites to enable a self funding program
- Access was supported by a 100+ global Medicine Access team with regional expertise to provide rapid response across multiple time zones

Access was supported by a 100+ global Medicine Access team

RESULTS

Clinigen provided access to **130+** patients across Europe, Asia and Latin America involving more than **90 treating physicians**.



BENEFITS

FOR PATIENTS

• Were able to gain access to lifesaving medicine prior to commercial launch

FOR HCPs

• Received support on the access process to enable them to confidently use this new medicine, while gaining simple and rapid treatment for their patients

• A long term solution that provided the medicine for multiple patients under their care

FOR THE COMPANY

• Responded to global requests for access no matter where the request came from meaning no eligible patient was left untreated

• Implemented a self-funding long term solution that helped patients over the longer term

• Were able to remain focused on gaining EU approval with the knowledge that their expert partner was handling global early access

Pitcairn House
Crown Square
First Avenue
Burton-on-Trent
DE14 2WW
United Kingdom

+44 1283 495010
+44 1283 494341
info@clinigengroup.com

790 Township Line Road
Suite 120
Yardley
PA 19067
United States

+1 215 944 8800
+1 215 944 8661
info@clinigengroup.com

CLINIGEN

www.clinigengroup.com

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