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Groundbreaking Rare Disease Drug Approval (OGSIVEO® [nirogacestat]) Propelled by Expert Regulatory Strategy and Program Management

SITUATION

SpringWorks Therapeutics (SpringWorks), a biopharmaceutical company that applies a precision medicine approach to developing and delivering life-changing medicines, acquired Pfizer's asset to begin their pivotal clinical study in desmoid tumors.

SpringWorks needed to refine their late-stage regulatory strategy considering Pfizer's previous development (plus compelling results from an investigator-initiated trial putting them at End of Phase 2 (EOP2)), define a clear development roadmap to approval, and submit a New Drug Application (NDA).

CHALLENGE

At the time, the company was a small startup with no in-house regulatory team to bring their Phase 2 asset to market.

SpringWorks approached Halloran for regulatory strategy and execution support to submit their initial Investigational New Drug (IND) for desmoid tumor and eventually their NDA, and then required a program manager with deep-rooted NDA experience and expertise.

SOLUTION

Halloran employed the following regulatory strategies to advance the nirogacestat drug development program:

- Led and managed the following advice meetings [15+] with the Agency:
  - ✓ Pre-IND / End-of-Phase 2
  - ✓ Type B
  - ✓ Type C
  - ✓ Type D
  - ✓ Preliminary Breakthrough Therapy Designation Advice
  - ✓ Comprehensive Multidisciplinary Breakthrough Therapy
  - ✓ Pre-NDA
- Sought and successfully obtained the following regulatory designations:
  - ✓ Orphan Drug
  - ✓ Fast Track
  - ✓ Breakthrough Therapy
  - ✓ Real-Time Oncology Review (RTOR)
  - ✓ Priority Review

To translate the regulatory strategy into essential actionable elements, the client relied on program management to create outcome-driven plans to efficiently and effectively execute as a team.

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Translated Regulatory Strategy into Actionable Plan

- Transformed the integrated development strategy into a visual and actionable roadmap
- Provided proactive strategic planning by anticipating change and appropriate responses
- Focused team to prioritize activities and remove barriers
- Drove strategic goals while problem-solving day-to-day issues related to resource, time, and quality
- Utilized adaptive program management approach and techniques to create outcome driven plans

Provided Cross-Functional Coordination and Infrastructure

- Created a governance structure to enable efficient workstream deliverables
- Provided team direction to collaborate through a shared vision and alignment
- Created and developed integrated timelines while adapting to changes via scenario planning
- Created dashboards, reports, and trackers to show progress, risks, and mitigation plans in a consolidated, centralized structure

Enhanced Communication and Collaboration

- Elevated best practices for optimal communication for stakeholders across the company
- Implementation of lessons learned with actionable solutions to apply to a future NDA

Results

Halloran's regulatory strategy and program management expertise enabled Springworks' product development timeline to progress from Pre-IND (EOP2) to approval in just six years. Halloran took full advantage of the benefits of the regulatory designations and led frequent interactions with the FDA every step of the way (over 15+ meetings), fostering development success and product approval.

Our Expertise

Regulatory Strategy

In the rapidly evolving landscape of product development, strategic advising emerges as a critical service for navigating through the discovery, preclinical, clinical, and commercial lifecycle phases. We offer cutting-edge industry-leading strategic advising to address the multifaceted challenges companies face, including regulatory hurdles. By offering expert guidance at each lifecycle inflection point, our strategic advisors listen to your company's goals and objectives and offer strategies tailored to meet your needs.

Strategic Program Leadership and Management

Life science leaders are responsible for defining their corporate strategy and goals throughout the development lifecycle, but the program team is responsible for defining and executing the plan to achieve these goals. As integral members of your team, our Program Managers ensure that you possess a blend of technical expertise, interpersonal skills, and training necessary to forge a high-performing team and aligns with your business goals and requirements.

To learn more about our services visit our website at hallorancg.com

ABOUT OUR CONTRIBUTORS:

CANDICE MONTAGNA, MS, RAC

Associate Principal Consultant

Candice has a 24-year Regulatory Affairs career in the biopharma industry with an emphasis on late-stage development. She has expertise in Regulatory strategy, Regulatory execution, and Regulatory operations for pharmaceuticals and biologics. She has extensive experience in developing the highest quality investigational (IND/CTA) and marketing (NDA/BLA/MAA) submissions in eCTD format for global health authority approval. She has proficiency in Regulatory designations (Orphan, Fast Track, Breakthrough Therapy, and Priority Review) as well as Real-Time Oncology Review, Rolling Review, and Accelerated Approval. She has been the Regulatory lead for 30+ FDA meetings (Types A-C, including Pre-IND, EOP1, EOP2, Pre-NDA/Pre-BLA, and BTDR Preliminary Advice) and 1 EU Scientific Advice meeting with MHRA (UK) across multiple therapeutic areas (rare oncology, immuno-oncology, cardiovascular, anti-infective, and insomnia).

CAROLINA AHRENDT, MBA, PMP

Principal Consultant

Carolina Ahrendt has over 20 years of experience in program and portfolio management for developing pharmaceuticals and biologics across multiple therapeutic areas. She has provided program leadership in all phases of development and managed numerous INDs, BLAs, and NDAs. She has extensive knowledge in guiding cross-functional teams with strategic planning, marketing application preparation, and integrated development plan analysis throughout the product life cycle (from early to late-stage development). Carolina has supported programs in therapeutic areas such as diabetes, inflammation, oncology, ophthalmology, pain, rare diseases, schizophrenia, and viruses.