Goodwin FDA Drug and Biologic Development Scorecard

Pre-IND

- ☐ Met with FDA for pre-IND meeting?
- ☐ Considered orphan drug designation?
- ☐ Considered fast track designation?
- ☐ Considered 3- and 5-year exclusivity?
- ☐ Considered 505(b)(2) or biosimilar strategy?
- ☐ Identified endpoints for clinical trials? Any novel endpoints?
- ☐ Identified similar FDA precedents that may inform development?
- ☐ Identified clinical research organization and sites? Negotiated agreements?
- ☐ Considered combination synergies and potential collaboration partners?
- ☐ Prepared IRB and informed consent documentation?
- ☐ Identified manufacturing partner or ramped-up in-house manufacturing?

Phase 1

- ☐ Considered additional opportunities for FDA feedback, including Type C meetings?
- ☐ Assessed eligibility for QIDP or rare pediatric disease designation?
- ☐ Determined initial safety profile and dosage?
- ☐ Submitted applicable trials to ClinicalTrials.gov?
- ☐ Prepared patient advocacy strategy?
- ☐ Considered Phase 2/3 enrichment strategies and trial design?
- ☐ Secured GMP materials for Phase 2?
- ☐ Identified publication and medical congress opportunities?

Phases 2 – 3

- ☐ Met with FDA for EOP2 meeting?
- ☐ Considered breakthrough or RMAT designation?
- ☐ Requested special protocol assessment?
- ☐ Made publicly available company's expanded access policy?
- ☐ Carefully considered preapproval and disease awareness communications?
- ☐ Assessed likelihood of REMS?
- ☐ If utilizing accelerated approval, designed confirmatory studies?
- ☐ Prepared for inspections?
- ☐ Addressed pediatric study requirements?
- ☐ Began drug naming process?
- ☐ Addressed any comparability or bridging issues?

Submission & FDA Review

- ☐ Met with FDA for pre-NDA/BLA meeting?
- ☐ Eligible for priority review? Submitted request?
- ☐ Eligible for pediatric, tropical disease, or MCM voucher? Submitted request?
- ☐ Assessed whether advisory committee likely? If so, begun preparing for advisory committee?
- ☐ Prepared for labeling and REMS negotiations?
- ☐ Submitted 120-day safety update?
- ☐ Complete response? Submitted formal dispute request?
- ☐ Ramped-up commercial production?
- ☐ Reviewed existing corporate website and corporate communications in anticipation of increased FDA scrutiny?

Marketing Ramp-Up

- ☐ Prepared launch materials?
- ☐ Assembled PRCs?
- ☐ Launched disease awareness materials?
- ☐ Addressed pricing and reimbursement issues?
- ☐ Developed a medical affairs strategy?
- ☐ Planned to file Orange/ Purple Book listings?
- ☐ Planned to submit patent term extension request?
- ☐ Considered drug sampling program build-out?
- ☐ Sunshine Act compliance ramp-up and compliance program build-out underway?
- ☐ Recruited or contracted a sales force and developed sales training materials?

KEY CONTACTS

ALEXANDER VAROND
Partner
+1 202 346 4064
avarond@goodwinlaw.com

JULIE TIBBETS
Partner
+1 202 346 4226
jtibbets@goodwinlaw.com

Let Goodwin's FDA team help you navigate uncertainty, expedite development, and achieve success.

Visit www.goodwinlaw.com/fda

GOODWIN