A Roadmap to Commercial Launch: Late Stage Drug Development

12–18 Months Before Commercial Launch

Commercial Contracting

- Establish commercial scale manufacturing and alternative sources and suppliers, as needed, by executing supply and quality agreements with API suppliers, finished dose manufacturers, packaging sites and other applicable parties
- Determine whether to, and identify, any third-party partners to out-license to or collaborate with for development or commercialization (including on a worldwide/regional basis for one or more indications)

Patent & IP Strategy

- Initiate IP lifecycle management before pivotal trials
- Prepare and submit Orange Book Form 3542a with NDA for small molecule therapies
- File patent applications related to the proposed FDA label, including safety, dosing and other key product attributes
- Confirm or file patent applications directed to final dose formulation
- Confirm applicable regulatory exclusivities

FDA

- Prepare for pre-NDA or pre-BLA meetings
- Plan strategy for FDA labeling negotiations
- Align product label with IP strategy and assess for products liability considerations
- Establish medical, legal, regulatory (MLR) committee and related policies for review of company communications and publications
- Initiate applications for state licenses and permits
- Plan for expanded access program, as applicable
- Onboard commercial and medical affairs team leaders to begin developing build-out plans

Healthcare Compliance & Regulatory

- Identify Compliance Officer and launch compliance committee
- Conduct initial risk assessment to identify compliance priorities and strategic objectives
- Prepare Code of Conduct and policies related to HCP interactions and physician-industry transparency
- Consider market access strategies, including participation in government programs such as Medicaid Drug Rebate Program, 340B Drug Pricing Program, Veteran's Healthcare Administration Drug Pricing Program, and Medicare Parts B and D

Products Liability & Insurance

- Evaluate and obtain clinical trial liability insurance policies, including determination of appropriate limits
- Establish protocols for notifying insurance carrier of study subject injury claims

< 12 Months Before Commercial Launch

Commercial Contracting

- Contract or onboard commercial sales representatives, marketing, field market access and medical affairs teams*
- Connect with marketing agency to manage launch activities*
- Negotiate payor, pharmaceutical benefit manager, wholesaler, distribution and specialty pharmacy agreements*
- Confirm patent assignments and licenses, inventor and consulting agreements
- Execute agreements, as applicable, for advisory board members, speaker programs, consultants/key opinion leaders, patient advocacy sponsorships, expanded access programs, continuing medical education and other related medical activities*

Patent & IP Strategy

- Prepare for and file trademarks on drug tradename
- Obtain and file further patent applications before launch
- Prepare for patent term extension filings within 60 days of FDA approval
- Prepare for and submit Orange Book patent listings Form 3542 for small molecule therapies within 30 days of FDA approval

FDA

- Develop commercially aligned key launch claims and materials; consider whether to seek FDA advisory comments
- Establish promotional review committee (PRC), if separate from the MLR committee, and related policies for review of promotional materials
- Establish call plans for appropriate specialties and approach to incentive compensation
- Retain and train sales force, medical science liaisons and managed markets personnel
- Develop speaker program materials; identify and train appropriate speakers
- Develop customer service call scripts and conduct training on complaint and adverse event intake
- Develop procedures for adverse event reporting and complaint handling
- Conduct mock pre-approval inspections and GCP audits of key clinical site pivotal trial records
- Prepare for REMS, registries or other post-marketing requirements, as applicable

Healthcare Compliance & Regulatory

- Develop processes to address core risk areas, including HCP contracts, incentive compensation for field personnel, grants and transparency reporting
- Launch initial compliance training for employees, including related certifications and conflict of interest disclosures
- Implement additional compliance policies (e.g., medical information requests, appropriate interactions between medical and commercial personnel)
- Address any anticipated market access strategy hurdles and execute market access, coverage, coding and reimbursement strategy (including government program participation)
- Assess hub services needs and develop patient assistance program materials and business rules (e.g., co-payment support, reimbursement advice, patient assistance program interactions, bridge programs, vouchers)
- Conduct meetings with payors and formulary committees
- Form and launch pricing committee and grant committee
- Ensure proper compendia reference price
- Develop price reporting capabilities for applicable federal healthcare programs and state drug transparency law compliance program

Products Liability & Insurance

- Establish protocols for claims resolution
- Establish protocols for monitoring signals for product safety
- Place product liability insurance for marketing post-approval, including determination of appropriate limits
- Develop procedures for notice to carriers in the event of product recalls, injuries or claims
- Confirm appropriate extended reporting period for clinical trial insurance

Looking to launch?
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* Denotes agreements that cover activities subject to potentially significant healthcare and FDA-related regulations, which may require input from those perspectives as well.