Solutions for Antiviral Drug Discovery and Development

The InnovaTID Pharmaceuticals Antiviral Consulting group has a deep understanding of the pharmaceutical value chain and can draw on broad experience in discovery, development, regulatory affairs, operations, and strategic planning. Our experts have worked at leading pharmaceutical and biotechnology companies, and have played critical roles in enabling FDA approval and launch of three HCV drugs [telaprevir (Incivek), boceprevir (Victrelis), and sofosbuvir (Sovaldi)], entecavir (Baraclude) for HBV, and amprenavir (Agenerase) and fosamprenavir (Lexiva) for HIV. Our unique blend of strategic vision, analytical capabilities, and operating experience positions us as ideal partners to help our clients achieve success in a broad range of R&D activities.

We tailor our antiviral services to the needs of our clients. Examples of our consultation services include grant applications, project management, smart assay and screening development, improvement of existing compounds and discovery of novel chemical entities, strategies to overcome antiviral resistance, design and execution of clinical development plans.

Core Team

Xiao Tong, PhD (Harvard University), Discovery and Clinical Virology
Xiao has over 15 years of experience in antiviral research and development at Pfizer, Schering-Plough/Merck, and Hoffmann-La Roche. Xiao was the lead biologist on the development and clinical team that discovered the HCV protease inhibitor Victrelis. She has also provided virology support to several HCV inhibitors in clinical development, as well as the influenza virus inhibitor Tamiflu. Xiao has over 40 publications in the field of virology and drug discovery.

Robert Hindes, MD (Rutgers Medical School), Infectious Disease Clinical Development
Bob did his Infectious Disease Fellowship at Harvard Medical School and New England Deaconess Hospital, and spent 12 years as a physician and clinical infectious disease researcher at Danbury Hospital and New York Medical College. After joining Bristol-Myers Squibb, Bob had a major role in the clinical development and successful NDA for Baraclude, a HBV polymerase inhibitor with >$1B annual sales, and was Medical Lead for all HCV antiviral drugs. As VP of Clinical Development at Pharmasset/Gilead, he was responsible for the Phase 2 and 3 programs for Sovaldi, a HCV polymerase inhibitor with >$2B sales in 3 months.

Ursula Germann, PhD (Universität Zürich), Oncology/Infectious Disease Discovery, Pharmacology, Preclinical Safety
Ursula has over 20 years of experience in Biochemistry, Molecular and Cell Biology, Pharmacology, Safety Pharmacology, and Discovery Toxicology. At Vertex Pharmaceuticals, Ursula contributed to the development and execution of a mouse model for influenza, which led to the selection of VX-787 as a clinical candidate (currently in Phase 2). She also contributed to the discovery of Incivek and over fifteen clinical candidates for the treatment of cancer and infectious, immune, and CNS diseases.

Ann D Kwong, PhD (University of Chicago), Founder and CEO
Ann developed the concept of InnovaTID (Innovative Thinking for Innovative Drugs) that informs all our activities. An industry leader with more than 20 years of experience in developing successful drug candidates, Ann played a leading role in the development of Incivek, an HCV protease inhibitor with >$2B in peak sales for Vertex Pharmaceuticals. She is a founder of HCV Drug Development Advisory Group, a consortium of industry, academic, community, and regulatory leaders working to optimize HCV drug development.
Antiviral Drug Discovery and Development Services

We have strong expertise and a proven track record in the areas of antiviral discovery and development shown below.

Consultation in Project Management and Leadership

**Therapeutic area leadership**
- New targets and licensing assets evaluation
- Lab design and start-up (BL2+ and BL3)
- Group/department building
- Preclinical candidate development

**Cross-functional project leadership**
- Discovery teams with biology, chemistry and DMPK expertise
- Development teams including toxicology and CMC support
- Clinical teams to progress candidate to regulatory approval

**Grants and collaborations**
- NIH grant applications
- Academic research collaborations
- CRO management (study proposals, budget, reports)

**Regulatory document preparation and application**
- Investigator brochure
- IND application and annual updates
- NDA, including Japan
- FDA correspondence and antiviral advisory committee hearings

Stage-Specific Expertise and Guidance

**Discovery**

**Antiviral Targets**
- Host factors (IMPDH)
- Viral targets
  - Herpesviruses (HSV, EBV)
  - Respiratory viruses (RSV, influenza, parainfluenza)
  - Hepatotropic viruses (HBV, HCV)
  - Papilloma viruses (HPV, BPV); and HIV

**Assay Development**
- Antiviral high throughput screening (HTS)
- Cell-based virus and replica assays
- *In vitro* replication assays (influenza, HCV, SV40)
- Enzymatic assays
  - Neuraminidase (influenza); Protease (HCV, HIV)
  - Helicase (HCV), Polymerase (HCV); Reverse transcriptase (HIV)

**MOA Studies**
- Time of Addition and virus lifecycle intervention
- Target identification using resistant variants
- Combination studies (synergy, additivity, antagonism)

**Development**

**Pharmacology/Pharmacodynamic Assays**
- Development of animal efficacy models (mouse models for HCV protease and influenza model)
- Analysis of clinical PK/PD relationship

**Clinical Virology**
- Sequence and phenotypic analysis of patients samples (HCV and influenza variants)
- Preparation of virology study reports
- Development of novel assays for detection of resistant viruses

**Resistance Studies**
- Selection and mapping of resistant variants
- Phenotypic characterization (change in sensitivity and viral fitness)

**Clinical Study Design**
- Phase 1 SAD/MAD/POC studies
- Phase 2 dose and duration selection studies
- Phase 3 NDA enabling studies

References