INTREPID Alliance Clinical Antiviral Landscape: Clinical Antiviral Compounds Analysis (January 2024)*

- Initial analysis of the clinical antiviral landscape data as of November 16, 2023 was posted on the INTREPID website on **January 24, 2024**.
  - Two rounds of rigorous scientific triage on 300 clinical phase entries reduced the number to 61 distinct compounds associated with 80 compound/indication pairings.

Initial Analysis

Exclusion Criteria:

- Antibodies
- Antibiotics & Anti-infectives
- Cell-based Therapy
- HIV or HCV-specific
- Host Targets (incl. Imm. Mod.)
- Natural Products/ Nutraceuticals/Herbals
- Vaccines

Inclusion Criteria:

- Known Antiviral MOA
- *In Vitro/In Vivo* Activity
- Small Molecules
- Peptides
- RNA-based
- SAD/MAD Data
- FIH Completed
- No Major Safety Signals

*As of November 16, 2023

INTREPID Alliance Clinical Antiviral Landscape: Clinical Antiviral Compounds Analysis (March 2024)*

- Further analysis investigated the clinical landscape with data updates from March 2024:
  - Novel Clinical Phase Antiviral Compounds (e.g., not yet approved for a virus disease indication)
  - Approved-Indication Expansion Antiviral Compounds (e.g., initial approval for one viral indication and under evaluation for other viral indication(s))
- Additional scientific analysis** of only the novel compounds categorized them as follows:
  - **Promising**
  - **Watch & Wait**
  - **Archived**
- Based on these analyses of the March 2024 data, there are 60 distinct antiviral compounds in the antiviral clinical development landscape.

*As of March 8, 2024; **See criteria and references on slide 6

Criteria* for Promising Clinical Antiviral Compound Analysis (March 2024)**

- FIH trial completed & data at adequate doses and dosing duration available
- POC study ongoing *or* completed & data available
  - POC demonstration via viral endpoint, symptom alleviation, etc.
  - POC in animal model may be applicable for certain viral diseases where clinical POC is not feasible
- Adequate PK/PD to support Phase 2/3 dose selection and route of administration
- Safety and tolerability consistent with the target dose/exposure and no difficult-to-manage clinical safety signals
- Other criteria such as chemical structure, synthesis, scalability, etc. are taken into account where data are available.

*In addition to the collective antiviral drug development experience of INTREPID member companies, guidance documents from Regulatory Authorities such as the US FDA routinely used by drug developers, and publicly available Target Product Profiles such as the NIH/NIAID Target Product Profiles for Antivirals, were used to inform the clinical phase triage.

**As of March 8, 2024; FIH: first-in-human; POC: proof-of-concept; PK/PD: pharmacokinetic/pharmacodynamic; CMC: chemistry, manufacturing, and controls

Categories for Clinical Antiviral Compound Analysis (March 2024)*

- **Promising** (e.g., meets "Promising Criteria")
  - 100DM Ready
  - Registration & Approval for established viral diseases
- **Watch & Wait**
  - FIH or POC Study just starting/ongoing or data are unavailable for a completed study
  - Unable to make a data-driven evaluation
- **Archived**
  - Development paused, no recent information >5 years
- **Exclude**
  - Known disqualifying data related to safety and tolerability, efficacy, developability, chemical structure, etc.

*As of March 8, 2024; FIH: first-in-human; POC: proof-of-concept

INTREPID ALLIANCE

INTERNATIONAL READINESS FOR PREVENTING INFECTIOUS VIRAL DISEASE

Interested in engaging with us?

To improve our listing, developers are invited to **submit non-confidential information on their compound candidates**. **In addition, we welcome all feedback through our online portal.**

For more information, contact nina@intrepidalliance.org.

intrepidalliance.org

linkedin.com/company/intrepid-alliance