Development of Antimicrobials and Broad-Spectrum Activity: Antibiotics

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Division of Microbiology and Infectious Diseases
NIAID, NIH, DHHS
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Continuous Support for Product Development

Product Development Pathway

- Basic Research
  - Hypothesis Development and Testing
- Research Tools and Technologies
- Preclinical Development
  - Discovery
  - IDE- and IND-Enabling Activities
- Clinical Evaluation
  - Trials
- Diagnostics
- Vaccines
- Therapeutics

- Preclinical development support for small molecules and biopharmaceuticals
- Product development support through Phase I clinical trials
Overlapping Support for Product Development

Basic  Translational  Clinical (Product Development)

Licensed Products

Grants  SBIR  Cooperative Agreements  Contracts

Commercial Development Activities

Phase IV

NIAID Scientific Activities

Phase II

Preclinical and Clinical Services
Grants: Biodefense Partnerships

Funding Sources

- RESEARCH
  - NIH, CDC, Other USG Entities, Academia, Private Sector

- ACQUISITION
  - SRF, DSNS, Pandemic Influenza Appropriations

- ADVANCED DEVELOPMENT
  - BARDA (including Pan Flu), Private Sector

Activities

- Basic Research
- Prototype Design or Discovery
- Preclinical Development
- Clinical Development

Product Development Stages

- Early Stage
- Mid Stage
- Late Stage
- Licensure

Contracts

SBIR
Contracts:
Broad Agency Announcement

- Office of Acquisitions conducts solicitation/award
- Proposal process:
  - Letter of Intent (no white paper)
  - Finite time to submit, proposals due within 45-90 days
  - Communication only with OA officials
    - Responses provided via BAA amendments
    - No contact with program staff during ‘open’ period
- Scientific Review Program conducts peer review
- Programmatic review based on portfolio balance, funding
- OA handles SOW negotiation; base + options structure
Finding information regarding Support Opportunities

Concepts: Potential Opportunities

Concepts represent early planning stages for initiatives: program announcements, requests for applications, and solicitations.

Approval of a concept by NIAID’s advisory Council does not guarantee it will become an initiative. We make that decision based on scientific and programmatic priorities and the availability of funds.

Concepts reveal possible initiatives or give you ideas for an investigator-initiated application. Read more in Concepts May Turn Into Initiatives and Choose Approach and Find FOAs in Part 2 of our Strategy for NIH Funding.

Below we post the concepts Council approves a few weeks after each advisory Council meeting—go to the Advisory Council portal for the schedule. To get an email alert when we post new concepts, sign up at NIAID Funding Newsletter and Email Alerts Subscription Center and pick Concepts, Potential Funding Opportunities as a topic of interest.

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Recent BAA solicitation for FY2013

Development of Therapeutics Medical Countermeasures for Biodefense and Emerging Infectious Diseases

Solicitation Number: BAA-NIAID-DMID-NIHAI2012149
Agency: Department of Health and Human Services
Office: National Institutes of Health
Location: National Institute of Allergy and Infectious Diseases

Solicitation Number: BAA-NIAID-DMID-NIHAI2012149
Notice Type: Combined Synopsis/Solicitation
Product Development Contracts: Therapeutics (2003-present)
### Product Development BAA: Broad Spectrum Therapeutics

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<tr>
<th>Company</th>
<th>Product</th>
<th>BioD Indication</th>
<th>Public Health Indication</th>
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<td>Achaogen</td>
<td>Novel Aminoglycoside</td>
<td>i.v. Rx for: Y. pestis, F. tularensis</td>
<td>Gram neg. (Klebsiella, Acinetobacter, Pseudomonas)</td>
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<td>Trius</td>
<td>Small molecule dual targeted inhibitor of DNA synthesis</td>
<td>i.v. Rx for: Y.pestis, F.tularensis, B.pseudomallei</td>
<td>Gram neg. and gram pos. CAP and UTI</td>
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<td>Enanta</td>
<td>Bicycolide (macrolide)</td>
<td>i.v. and oral Rx for: B.anthracis</td>
<td>Gram pos. CABP, MRSA</td>
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<td>CUBRC/Tetraphase</td>
<td>Novel Tetracycline</td>
<td>i.v. and oral Rx for: Y. pestis, F.tularensis, B. anthracis</td>
<td>Gram pos. and gram neg. CABP</td>
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<td>Crucell</td>
<td>Monoclonal antibodies</td>
<td>i.v. Rx for: influenza A</td>
<td>B.S. against influenza A; co-formulate with MAb against influenza B for prophylaxis</td>
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<td>NexBio, Inc.</td>
<td>BS, host-targeted recombinant protein enzyme</td>
<td>Inhalation Rx for influenza A</td>
<td>B.S. activity against influenza A, B and parainfluenza</td>
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<td>Unither Virology, Inc.</td>
<td>BS, host-targeted iminosugar antiviral</td>
<td>i.v. and oral Rx for: Dengue</td>
<td>i.v. and oral for: Influenza</td>
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Preclinical Product Development Services

Therapeutics

In Vitro Assessment of Antimicrobial Activity

Interventional Agent

Biopharmaceutical Products

Vaccines

Testing

Chemistry, Manufacturing, and Controls (CMC) Documentation for IND

Manufacturing

Animal Models
Development of Interventional Agents: suite of services
Example: Clinical Formulation Development

- Developed a preliminary human clinical formulation
- Mock clinical capsules prepared and subjected to stability testing
- At accelerated temp/humidity (i.e., typical Brazil day), capsules with compound turned darker

Mutyam et al., AAPS Journal, 11, S2, #1425, 2009
UNITED THERAPEUTICS SUBSIDIARY ENTERS INTO CONTRACT WITH NATIONAL INSTITUTES OF HEALTH FOR AWARD OF UP TO $45 MILLION TO SUPPORT GLYCOBIOLOGY ANTIVIRAL PROGRAM

SILVER SPRING, Md., Oct. 10, 2011 /PRNewswire/ -- United Therapeutics Corporation (NASDAQ: UTHR) announced that its subsidiary, Unither Virology, LLC, has been awarded a contract for up to approximately $45 million under a Broad Agency Announcement from the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), for studies directed at the development of a broad-spectrum antiviral drug based on its glycobiology antiviral platform. Based

NIAID supported:

- Drug candidate synthesis to identify a lead
- Toxicity studies to establish preliminary safety
Development of Biopharmaceutical Products: suite of services

- Services available in 5 major areas
  - Feasibility assessments
  - Assay Development
  - Process Development
  - cGMP manufacturing
  - Regulatory Documentation Support
Gap-filling Resources for Researchers

Resources for Researchers

Microbiology and Infectious Diseases Resources
The Division of Microbiology and Infectious Diseases (DMID) supports extramural research to control and prevent diseases caused by virtually all human infectious agents except HIV.

Funding Opportunities
Apply for grants and contracts to conduct basic research, preclinical development, or clinical evaluation.
- NIH-Wide Funding Opportunity Announcements
- NIAID Funding Opportunity Announcements and Requests for Proposals

Product Development Services and Research Tools and Technologies
Request development by DMID-funded contractors of critical information needed to move a product through the product development pathway. Note: Services are contingent upon availability of required preliminary data.

Click on labels below to view services for diagnostics, vaccines, and therapeutics, and for basic research, preclinical development, and clinical evaluation.

Website Tools
- Email this page
- Print this page
- Get email updates
- Order publications
- Bookmark & share

Stay Connected
Facebook
Twitter
Google+
Flickr
YouTube

Contact Info
dmidresources@niaid.nih.gov

http://www3.niaid.nih.gov/LabsAndResources/resources/dmid/
Overcoming Bottlenecks in the Development of Therapeutics for Infectious Diseases

Bridging the Gap – Overcoming Bottlenecks in the Development of Therapeutics for Infectious Diseases

August 9-10, 2012
Rockville, MD

The Division of Microbiology and Infectious Diseases (DMID) at NIAID is committed to helping advance new therapeutics for infectious diseases through the product development pipeline. The three key objectives for this workshop are:

- Review the current state of the translational research enterprise from the perspective of all stakeholders
- Enable interaction between seasoned translational researchers and investigators who are new to product development and encourage new collaborations
- Brainstorm on innovative ways to address bottlenecks in product development and consider new ways to capitalize on existing resources
Resources for Researchers
Microbiology and Infectious Diseases Resources

http://www.niaid.nih.gov/labsandresources/resources/dmid/Pages/default.aspx

THANK YOU!

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