

## METHODS OF ANALYZING VIRUS-DERIVED THERAPEUTICS

### SUMMARY

Researchers at the National Cancer Institute's Biopharmaceutical Development Program recently developed massively parallel sequencing methods for virus-derived therapeutics such as viral vaccines and oncolytic immunotherapies. The methods allow for the determination of micro-heterogeneity and quantitation of low frequency sequence variants, which have the possibility of supplanting monkey neurovirulence safety testing (MNVT), mutant analysis by PCR, and restriction enzyme cleavage (MAPREC) methods that are currently used to screen RNA virus-derived therapeutics. The technology is currently in clinical stage.

### REFERENCE NUMBER

E-240-2015

### PRODUCT TYPE

- Diagnostics

### KEYWORDS

- massively parallel sequencing, virus-derived therapeutic, viral vaccines, oncolytic immunotherapy,
- monkey neurovirulence safety testing, MNVT, mutant analysis, restriction enzyme cleavage, MAPREC
- RNA virus-derived

### COLLABORATION OPPORTUNITY

This invention is available for licensing and co-development.

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### DESCRIPTION OF TECHNOLOGY

Researchers at the [National Cancer Institute's Biopharmaceutical Development Program](#) recently developed massively parallel sequencing methods for virus-derived therapeutics such as viral vaccines and oncolytic immunotherapies. The methods allow for the determination of micro-heterogeneity and quantitation of low frequency sequence variants, which have the possibility of supplanting monkey neurovirulence safety testing (MNVT), mutant analysis by PCR, and restriction enzyme cleavage (MAPREC) methods that are currently used to screen RNA virus-derived therapeutics. The technology is currently in clinical stage.

## Development Stage:

Clinical Phase I

## POTENTIAL COMMERCIAL APPLICATIONS

- Improved methods for detecting mutations in GMP-manufactured virus-derived therapeutics, including viruses, viral template plasmids, or vaccines;
- The method allows for at least two different virus-derived therapeutics to be assayed simultaneously.

## COMPETITIVE ADVANTAGES

- Provides a cost- and time-effective means of assaying a virus-derived therapeutic, such as oncolytic viruses, for viral sequence variants, for regulatory approval;
- RNA virus preparation steps increase the amount of viral RNA obtained;
- Demonstrated superiority of massively parallel sequencing ("MPS") over mutant analysis by PCR and restriction enzyme cleavage ("MAPREC") analysis.

## INVENTOR(S)

[Trevor Broadt \(NCI\)](#), Michael D. Harwich (American International Biotechnology, LLC), William T. Budd (American International Biotechnology, LLC), Gregory A. Myers (American International Biotechnology, LLC)

## DEVELOPMENT STAGE

- Clinical

## PATENT STATUS

- **U.S. Provisional:** US Provisional Patent App. No. 62/199,663, filed July 31, 2015
- **Foreign Filed:** International Patent App. No. PCT/US2016/044788, filed July 29, 2016

## RELATED TECHNOLOGIES

- [E-267-2014 - Processes for Producing and Purifying Nucleic Acid-Containing Compositions](#)

## THERAPEUTIC AREA

- Cancer/Neoplasm
- Immune System and Inflammation
- Infectious Diseases