

STATEMENT ON A NONPROPRIETARY NAME ADOPTED BY THE USAN COUNCIL

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| USAN | TERGENPUMATUCEL-L |
| PRONUNCIATION | ter" jen pum a too sel - el |
| THERAPEUTIC CLAIM | Cellular immunotherapy for the treatment of lung carcinoma |

CHEMICAL DESCRIPTION

HyperAcute[®]-Lung is a live, whole cell immunotherapy product for use in patients diagnosed with Stage IIIB or IV carcinoma of the lung that is produced by NewLink Genetics. The cancer vaccine consists of equal doses of three allogeneic human lung cancer cell lines (HAL1, HAL2 and HAL3) engineered to express the murine alpha-(1,3)-galactosyltransferase gene.

STRUCTURAL FORMULA

The gene modification is mediated by stable insertion via transduction with a replication-defective Moloney Murine Leukemia Virus (MMLV) vector containing a copy of the murine alpha-(1,3) galactosyltransferase gene expressed under the control of a cloned copy of the CMV Immediate Early Promoter. The modifying vector is designated LNCKG to reflect its derivation from the widely distributed LNCX vector and contains the same nucleotide sequence as predicted from cloned plasmid in which it was initially constructed. The drug product derives from a Master Cell Bank consisting of a large polyclonal population of transduced cells selected on the basis of expression of the inserted transgene as measured by the presence of alpha-(1,3)-galactosyl residues on the cell surface.

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| TRADEMARK | HyperAcute-Lung [™] |
| SPONSOR | NewLink Genetics |
| CODE DESIGNATION | HAL |