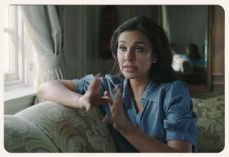
PREPARED FOR SECRETARY ROBERT F. KENNEDY JR. AND THE CHIEF OF POLICY · SEPTEMBER 2026

Killing Cancer

Six lives. One immune system. Not another drug.

Chemotherapy poisons the tumor and the patient. **Anktiva** (N-803, ImmunityBio) is an IL-15 signal that tells the body to make more of the cells that already kill cancer. **Approved** for one cancer, April 2024. **Not approved** for anything else in this film. The number to watch is the absolute lymphocyte count.

Justin
Bladder cancer · Syracuse, NY
UNDER THE FDA APPROVAL



Lisa
Multiple myeloma · Actress, TV host
NK-CELL TRIAL

Valerie
Metastatic lung cancer · Grandmother
TRIAL: KEYTRUDA + N-803

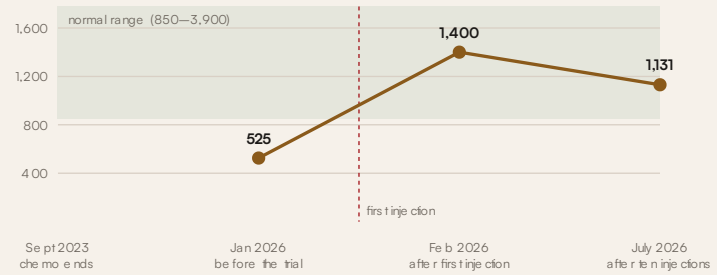
Andrew
Glioblastoma · Touring production
INVESTIGATIONAL

Alan
Recurrent prostate cancer · Entrepreneur
INVESTIGATIONAL

Beth
Stage 3 colon cancer · lymphopenia · 65
TRIAL: CHAN SOON-SHIONG INST.

The number nobody was reading

Two years after chemotherapy, and after every integrative therapy available, Beth's total lymphocytes sat at 525. One Anktiva injection in February 2026 took them to 1,400; they have held in the normal range since, 1,131 in July 2026.



Total lymphocytes, cells/µL, from Beth Kompothecras's own bloodwork. Severe lymphopenia is ≤500; below the 850 reference floor is lymphopenic.

Where the FDA stands today

APPROVED	BCG-unresponsive non-muscle invasive bladder cancer with carcinoma in situ, April 22, 2024. Justin's chapter.
UNDER REVIEW	Papillary bladder cancer supplement accepted; decision date January 6, 2027, on a standard clock.
NOT APPROVED	Lymphopenia reversal: RMAT designation (Feb 2025) and Expanded Access (June 2025). Beth's, Alan's and the pancreatic patients' use.
NOT APPROVED	Glioblastoma, lung, myeloma, prostate, Long COVID: clinical trials only. Andrew, Valerie, Lisa, Alan and Beth.

HR 0.46

Advanced pancreatic cancer: patients whose lymphocytes recovered above 1,000 on Anktiva lived significantly longer (QUILT-88, ASCO 2025).

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Recurrent glioblastoma patients alive at the January 2026 cutoff on the chemotherapy-free regimen Andrew describes.

Three things these six patients would ask of the Secretary

Each uses an authority HHS already holds. None requires new law.

01

Make the lymphocyte count a monitored vital sign in cancer care.

There is a national guideline for chemotherapy-induced neutropenia. There is none for lymphopenia, though the number is on every routine blood panel.

Lever: NCI and CDC convene NCCN and ASCO to add ALC monitoring, with a threshold for action, to survivorship and supportive-care guidance.

02

Use the expedited tools the FDA has already granted.

RMAT designation makes the lymphopenia indication eligible for priority review and accelerated approval by statute.

Lever: FDA agrees an accelerated pathway with lymphocyte recovery as the endpoint, and moves the papillary supplement from a ten-month standard clock to six-month priority review.

03

Pay for it while the evidence is collected.

Medicare can cover a therapy on condition of registry enrollment under Coverage with Evidence Development.

Lever: CMS opens a national coverage determination with CED for Anktiva in chemotherapy-induced lymphopenia, tied to the June 2025 Expanded Access authorization.

And meet them. Justin, Lisa, Valerie, Andrew, Alan and Beth are alive and willing to sit across a table. Thirty minutes with them will do more than any deck.

Scan for the full presentation — all six interviews in the patients' own words, the narrated eleven-minute film, the family statement, and every source linked.

Presented by Dr. Gary Kompothecras and Beth Kompothecras · Sarasota, Florida

Sources (full links in the presentation): FDA approval, Apr 22 2024 — fda.gov/drugs/resources-information-approved-drugs/fda-approves-nogapendekin-alfa-inbakicept-pmln-bcg-unresponsive-non-muscle-invasive-bladder-cancer · sBLA acceptance — ir.immunitybio.com/news-releases/news-release-details/immunitybio-announces-fda-acceptance-supplemental-bla-anktivar · RMAT, Expanded Access, QUILT-88, glioblastoma — immunitybio.com · Lymphopenia review — pmc.ncbi.nlm.nih.gov/articles/PMC6437964 · NCCN — nccn.org/guidelines/guidelines-detail?category=3&id=1493 · ASCO — asco.org/abstracts-presentations/ABSTRACT311323 · FDA RMAT guidance — fda.gov/regulatory-information/search-fda-guidance-documents/expedited-programs-regenerative-medicine-therapies-serious-conditions-0 · Priority review — fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/priority-review · CMS CED — cms.gov/medicare/coverage/evidence