



OSTEOSARCOMA
COLLABORATIVE
IMPACT STATEMENT
2022



Dear Friends of The Osteosarcoma Collaborative,

In 2018, The Osteosarcoma Collaborative and St Baldrick's Foundation pursued an initiative to raise \$1.5 million through a series of annual fundraising events in Arlington, Virginia in honor of local OsteoWarriors Olivia, John and Quinn. These brave children helped hundreds of other children and their families understand the importance of finding a cure for this devastating disease.

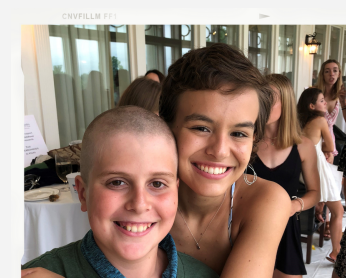
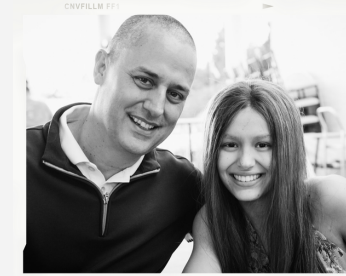
Osteosarcoma is an aggressive form of bone cancer that disproportionately impacts children and adolescents. There has been no advance in treatment for osteosarcoma since the advent of highly toxic chemotherapy over forty years ago, and survival rates for metastatic osteosarcoma have not improved as a result.

The purpose of this initiative was to fund a significant 3-year grant that would create multiple translational clinical trial opportunities in osteosarcoma. That goal was achieved first by identifying a grant to fund by using a rigorous, competitive, winner-take-all, application and scientific review process. The application call alone energized the osteosarcoma research community and we attracted 60 proposals. Then we fully funded the grant within two years after the initiative started. Within a few short months in 2018 we were able to start funding impactful research.

Dr. Alex Huang and his team at the Center for Pediatric Immunotherapy at UH Rainbow Babies and Children's Hospital and the Case Comprehensive Cancer Center won the award and immediately got to work bringing several immune modulating therapies as described below. The focus of Dr Huang's laboratory centered on enhancing the effectiveness and efficacy of immunotherapies against osteosarcoma through a multi-pronged approach that addresses tumor-intrinsic and extrinsic immune-related factors. We describe these advances in the impact report below.

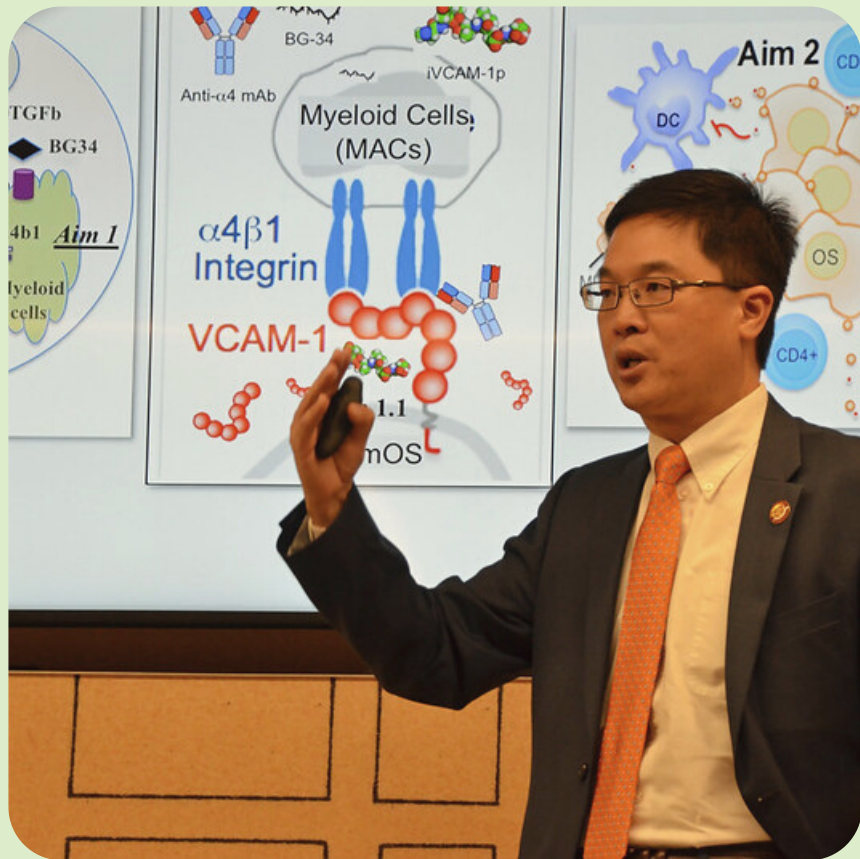
Thank you to all who joined us on this journey - the outpouring of love that fueled this support not only lifted the spirits of our OsteoWarriors and their families, but they funded one of the largest community-based grants to support osteosarcoma research, and we are currently working towards repeating the effort.

Michael Egge, Founding Member



Research to

Results



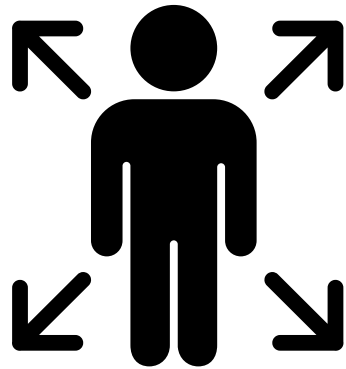
We are witnessing a cancer therapy revolution.

“Novel immunotherapies give us unprecedented opportunity to apply these strategies to treat pediatric patients affected by the most devastating solid tumor cancers. I truly believe a new efficacious therapy for metastatic osteosarcoma is not far into the future. With this high aspiration and mission, our team is focused on providing scientific insights regarding how the immune system operates within the osteosarcoma tumor microenvironment.

The St. Baldrick's Foundation-Osteosarcoma Collaborative Impact Award allows me the resources and freedom to pursue exciting scientific discoveries and possible translational angles wherever such opportunities take us. This has greatly expedited many of our ongoing collaborations with investigators as well as pharmaceutical companies.”

**Alex Huang, M.D., Ph.D., Case Western Reserve University,
UH Rainbow Babies & Children's Hospital**

THE IMPACT OF YOUR SUPPORT



1

Opened a Phase 1 clinical trial for pulmonary metastatic osteosarcoma based on a new understanding of factors that are critical for tumor cells to survive.

2

Discovered that a sugar on the outer shell of the oat bran can stop tumor growth, leading to Orphan Drug Designation and Rare Disease Designation by the FDA for use as an osteosarcoma treatment.

3

Provided data supporting the use of an existing drug being tested in adult cancers for pediatric osteosarcoma treatment, leading to Orphan Drug Designation by the FDA for use as an osteosarcoma treatment.

4

Currently developing two future clinical trials for advanced osteosarcoma treatment.

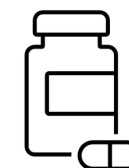
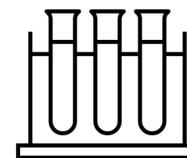
1

Opened a Phase 1 clinical trial for pulmonary metastatic osteosarcoma

Dr. Huang's team of 15 researchers performed all the underlying lab research work and generated the necessary data to bring Natalizumab to Phase 1 clinical trials.



Dr. Huang's team improved the understanding of how tumor cells survive and established new targets for therapy. They found that natalizumab, an already FDA-approved drug, attacks these targets and, therefore, may effectively treat pediatric sarcoma.



*Natalizumab works to affect white blood cells and reduce function of immune suppressive cells.

2

Borrowing nature's own immunotherapeutic agents to activate our body's immune system



Dr. Huang's team identified a naturally derived compound from oat bran as a potential novel cancer therapeutic.

It turns out that a sugar on the outer shell of the oat is highly immunogenic and can stop tumor growth in mouse models of osteosarcoma by eliciting robust anti-tumor immune responses.

Additionally, Dr. Huang's research team and Biomedical Engineering collaborator at Case Western Reserve University performed the work to refine this naturally derived sugar for treatment. This work resulted in a canine Phase I clinical trial with the NCI to treat pet dog patients with metastatic osteosarcoma.

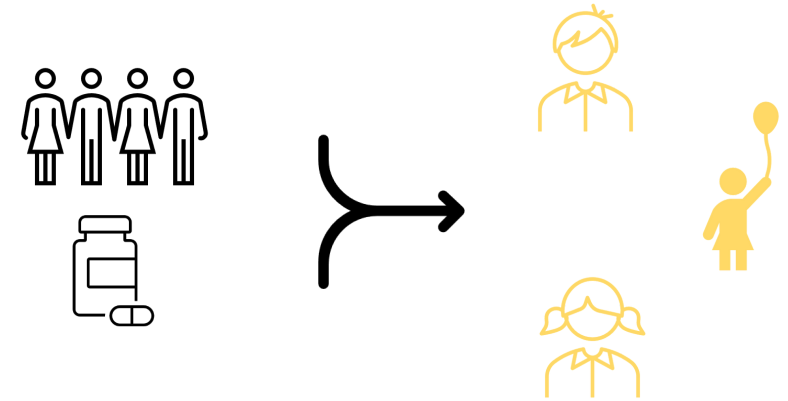
3

Using an existing adult cancer drug to treat pediatric osteosarcoma

Dr. Huang's research team developed data to show that the existing adult cancer drug, Vactosertib, is effective in advanced pediatric osteosarcoma.

Based on this information, the drug company that developed it applied for and was officially granted IND (Investigational New Drug) approval in August of 2022.

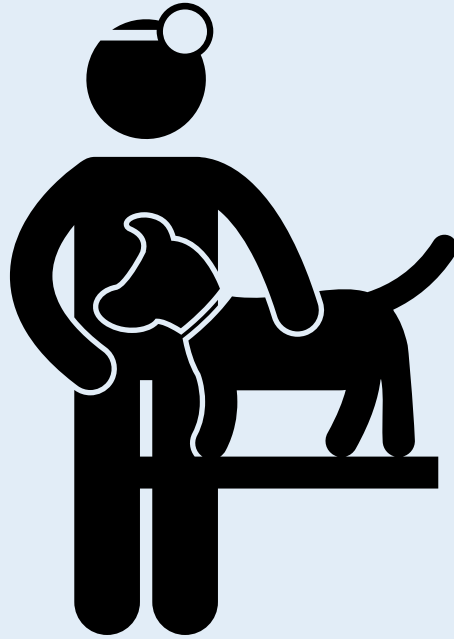
Osteosarcoma produces large quantities of Transforming Growth Factor-beta (TGF-B) which facilitates tumor growth. T cells and NK cells are part of the immune system that play a critical role in immunotherapy treatment, and TGF-B is a strong inhibitor of their function. Vactosertib is effective against TGF-B. Dr. Huang's team demonstrated that Vactosertib directly reduces osteosarcoma cell growth while enhancing the damage T cells and NK cells can do to tumor cells.



The research team has facilitated two separate compassionate use authorization requests of Vactosertib for two pediatric patients with refractory and metastatic osteosarcoma.

4

Clinical trials in the works



Large dogs can also be diagnosed with osteosarcoma.

Dr. Huang's team is actively collaborating with other institutions on a recently opened Phase I pet dog trial to use the naturally derived oat compound in pulmonary metastatic osteosarcoma canine patients.

This pet dog trial will gather data to apply this treatment in a Phase 1 human clinical trial for osteosarcoma.

Dr. Huang's team is also actively working to develop a Phase I/II clinical trial for the use of Vactosertib in pediatric patients, with a goal of submission in late 2022.

We are inspired by the progress Dr. Huang's team has made in such a short time.

BECAUSE OF THIS WE ARE READY TO DO IT AGAIN.



St. Baldrick's Foundation, The Osteosarcoma Collaborative and others are currently fundraising to support a second call for research applications, aiming to make even more of an impact for children with osteosarcoma.

IMMENSE GRATITUDE

We are sincerely thankful to every donor.

Your support for this powerful research gives hope to children with osteosarcoma.
Because of you we are seeing the first real progress in decades.



"Heartfelt thanks for the generosity of everyone involved in the fundraising and awareness efforts as we work together to fund and find a cure for the disease that took the life of my sweet niece, Caroline."

**Katherine Lugar,
St. Baldrick's Board Chair, 2019-2022**



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thank you!



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Sincere thanks also to the many other donors and volunteers who made this research possible.