UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **December 11, 2025**

ANIXA BIOSCIENCES, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-37492**	**11-2622630**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

3150 Almaden Expressway, Suite 250 San Jose, CA	**95118**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(408) 708-9808**

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation to the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.01 per share	ANIX	The NASDAQ Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01. Regulation FD Disclosure.

On December 11, 2025, Anixa Biosciences, Inc. ("we," "us," "our," or the "Company") issued a press release announcing that the Company and The Cleveland Clinic Foundation ("Cleveland Clinic") presented final data from the Phase 1 clinical trial of its investigational breast cancer vaccine. The press release, which is furnished as Exhibit 99.1 hereto, was issued following a presentation made by Justin Johnson, Ph.D., Program Manager at Cleveland Clinic and co-inventor of the breast cancer vaccine technology. Furnished hereto as Exhibit 99.2 is the presentation abstract utilized by Dr. Johnson for the presentation.

Statements that are not historical fact may be considered forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are not statements of historical facts, but rather reflect our current expectations concerning future events and results. We generally use the words "believes," "expects," "intends," "plans," "anticipates," "likely," "will" and similar expressions to identify forward-looking statements. Such forward-looking statements, including those concerning our clinical trials, involve risks, uncertainties and other factors, some of which are beyond our control, which may cause our actual results, performance or achievements, or industry results, to be materially different from any future results, performance, or achievements expressed or implied by such forward-looking statements. These risks, uncertainties and factors include, but are not limited to, those factors set forth in "Item 1A - Risk Factors" and other sections of our most recent Annual Report on Form 10-K as well as in our Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. We undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law. You are cautioned not to unduly rely on such forward-looking statements when evaluating the information presented in this Current Report.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

The following exhibits are filed with this Current Report on Form 8-K:

Exhibit No.	Description
99.1	Press Release
99.2	Presentation
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: December 11, 2025

ANIXA BIOSCIENCES, INC.

By: */s/ Michael J. Catelani*
Name: Michael J. Catelani
Title: President, Chief Operating Officer and Chief Financial Officer

Exhibit 99.1

Anixa Biosciences Announces Positive Phase 1 Data for Investigational Breast Cancer Vaccine; Primary Endpoints Were Met and Immune Response Observed in 74% of Participants

Vaccine Was Safe and Well Tolerated at the Maximum Tolerated Dose

Results Support Advancement of the Program into Phase 2 Development

Combination of Keytruda® and the vaccine generated T cell responses and showed no major additional side effects, supporting plans for a Phase 2 neoadjuvant combination study in newly diagnosed breast cancer patients

SAN JOSE, Calif., December 11, 2025 — Anixa Biosciences, Inc. ("Anixa" or the "Company") (NASDAQ: ANIX), a biotechnology company focused on the treatment and prevention of cancer, today announced the presentation of final data from the Phase 1 clinical trial of its investigational breast cancer vaccine (NCT04674306) at the 2025 San Antonio Breast Cancer Symposium (SABCS). The trial was conducted in collaboration with Cleveland Clinic and funded by a grant from the U.S. Department of Defense.

Final Phase 1 findings showed the investigational vaccine met all major primary endpoints, was safe and well tolerated at the maximum tolerated dose (MTD), and elicited protocol-defined immune responses in 74% of participants. The presentation, titled "Final Results of a Phase I Trial of Alpha-lactalbumin (aLA) Vaccine for Breast Cancer," was delivered by Justin Johnson, Ph.D., Program Manager at Cleveland Clinic and co-inventor of the breast cancer vaccine technology. The SABCS poster presentation is available at https://ir.anixa.com/events.

"Triple-negative breast cancer remains one of the most challenging subtypes to address, and Phase 1 trials are an important step in determining whether a new approach can be administered safely and activate the immune system as intended," said G. Thomas Budd, M.D., of Cleveland Clinic's Cancer Institute and principal investigator of the study. "In this trial, the investigational α-lactalbumin vaccine was safe and well tolerated at the maximum tolerated dose and generated protocol-defined immune responses in 74% of participants—results that support continued clinical evaluation."

Topline Phase 1 results:

- All major primary endpoints were met
- 74% of participants demonstrated protocol-defined immune responses; α-lactalbumin (aLA)-specific T cell responses were observed per protocol-defined criteria
- Vaccine was safe and well tolerated at the MTD, with adverse events primarily injection-site irritation

- Preliminary Immunohistochemistry (IHC) of primary tumors showed aLA expression ranging from absent to strong; analyses correlating expression to immune response and clinical outcomes are ongoing
- Participants will be followed for five years after completing the study
- Combination of Keytruda and the vaccine also generated antigen-specific T cell responses and showed no major additional side effects
- Data will inform planned Phase 2 study design, including a potential Phase 2 combination study with Keytruda in the neoadjuvant setting among newly diagnosed breast cancer patients

The Phase 1 study evaluated safety and monitored immune response to an investigational vaccine targeting α-lactalbumin (aLA). The trial enrolled 35 participants across three cohorts: Cohort Ia (n=26), women who completed standard-of-care treatment, including surgery, for early-stage TNBC within three years and were tumor-free but at elevated risk of recurrence; Cohort Ib (n=4), cancer-free women with BRCA1, BRCA2, or PALB2 mutations who elected preventive mastectomy and were vaccinated prior to surgery; and Cohort Ic (n=5), women with TNBC receiving pembrolizumab (Keytruda) in the adjuvant (post-surgery) setting, with evaluation of safety of combination administration and immune responses.

In Cohort Ia, at the MTD, the vaccine was reported as safe, with no flu-like symptoms (fever and myalgias), no abnormal clinical laboratory tests, and no other observed adverse side effects in this cohort; the primary notable adverse event was injection-site irritation. Participants demonstrated aLA-specific T cell responses, including production of interferon gamma and interleukin-17.

In Cohort Ib, safety and tolerability were similar to Cohort Ia. Immunohistochemistry analyses of resected breast tissue are ongoing and will be presented in a future scientific presentation.

In Cohort Ic, a key objective was to assess whether administration of the investigational vaccine in combination with pembrolizumab could create intolerable side effects. No major adverse side effects were reported; as in other cohorts, the primary adverse event was injection-site irritation. Two participants experienced Grade 3 adverse events consisting of greater irritation at an injection site.

The investigational vaccine targets α-lactalbumin, a lactation protein generally expressed in the breast during lactation but not at other times in life or in other normal tissues. In many breast cancers, malignant cells express α-lactalbumin. The vaccine is designed to activate the immune system to direct cytotoxic T cells toward tumor cells expressing α-lactalbumin, with the goal of providing preemptive immune protection against emerging tumors that express this antigen.

The vaccine is based on preclinical research led by the late Vincent Tuohy, Ph.D., who served as the Mort and Iris November Distinguished Chair in Innovative Breast Cancer Research at Cleveland Clinic.

“It was Dr. Tuohy’s hope that this vaccine would demonstrate the potential of immunization as a new way to combat breast cancer, and that a similar approach could someday be applied to other types of malignancies,” said Dr. Johnson. “Our findings that the majority of participants across all three cohorts demonstrated an immune response to α-lactalbumin is an encouraging sign.”

Dr. Amit Kumar, Chairman and CEO of Anixa Biosciences, stated, “We are very encouraged that the final Phase 1 data met all major primary endpoints, with the vaccine demonstrating a favorable tolerability profile at the MTD and protocol-defined immune responses in the majority of participants. We appreciate the support provided through the U.S. Department of Defense grant that enabled this study in collaboration with Cleveland Clinic, and we look forward to engaging with regulators and advancing plans for a Phase 2 study.”

About Anixa Biosciences, Inc.

Anixa is a clinical-stage biotechnology company focused on the treatment and prevention of cancer. Anixa’s therapeutic portfolio consists of an ovarian cancer immunotherapy program being developed in collaboration with Moffitt Cancer Center, which uses a novel type of CAR-T, known as chimeric endocrine receptor-T cell (CER-T) technology. This technology is differentiated from other cell therapies as the natural ligand of the FSHR receptor, FSH, binds to the FSHR receptor on the tumor cell instead of an antibody fragment. Moffitt is a world leader in cancer immunotherapy treatments, pioneering next-generation cell therapies such as CAR-T, and tumor infiltrating lymphocytes (TILs) to harness the power of the immune system. The Company’s vaccine portfolio includes vaccines being developed in collaboration with Cleveland Clinic to treat and prevent breast cancer and ovarian cancer, as well as additional cancer vaccines to address many intractable cancers, including high incidence malignancies in lung, colon, and prostate. These vaccine technologies focus on immunizing against “retired” proteins that have been found to be expressed in certain forms of cancer. The breast and ovarian cancer vaccines were developed at Cleveland Clinic and exclusively licensed to Anixa. Cleveland Clinic is entitled to royalties and other commercialization revenues from the Company related to these vaccine technologies. Anixa’s unique business model of partnering with world-renowned research institutions on all stages of development allows the Company to continually examine emerging technologies in complementary fields for further development and commercialization. To learn more, visit www.anixa.com or follow Anixa on LinkedIn, X, Facebook and YouTube.

Forward-Looking Statements

Statements that are not historical fact may be considered forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are not statements of historical facts, but rather reflect Anixa’s current expectations concerning future events and results. We generally use the words “believes,” “expects,” “intends,” “plans,” “anticipates,” “likely,” “will” and similar expressions to identify forward-looking statements. Such forward-looking statements, including those concerning our expectations, involve risks, uncertainties and other factors, some of which are beyond our control, which may cause our actual results, performance or achievements, or industry results, to be materially different from any future results, performance, or achievements expressed or implied by such forward-looking statements. These risks, uncertainties and factors include, but are not limited to, those factors set forth in “Item 1A - Risk Factors” and other sections of our most recent Annual Report on Form 10-K as well as in our Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. We undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law. You are cautioned not to unduly rely on such forward-looking statements when evaluating the information presented in this press release.

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PS4-06-19

Final results of a Phase I trial of an alpha-lactalbumin (aLA) vaccine for breast cancer

Justin M. Johnson[1], Emily E. Rhoades[2], Holly B. Levengood[1], Azka Ali[2], Hannah Gilmore[3], Megan L. Kruse[2], Erin E. Roesch[2], Tiffany Onger[2], Brenna Elliott[2], Elena Haury[2], Carolyn Porvasnik[2], Tobey Young[4], Terri Coutee[5], Judith A. Fitzgerald[6], Thaddeus S. Stappenbeck[1], G. Thomas Budd[2]

[1]Department of Inflammation & Immunity, Lerner Research Institute, Cleveland Clinic, Cleveland, OH; [2]Taussig Cancer Institute, Cleveland Clinic, Cleveland, OH; [3]Robert J. Tomsich Pathology and Laboratory Medicine Institute, Cleveland Clinic, Cleveland, OH; [4]PrevivorsandsurvivorsCom, Inc., Delray Beach, FL; [5]DepCJourney Foundation, Duvall, WA; [6]Sisters4Prevention, West Palm Beach, FL

Abstract

Background: α-Lactalbumin (aLA) is expressed in lactating breasts and 70% of triple-negative breast cancer (TNBC) but not at other times or in other tissues. Based on the "retired protein hypothesis" vaccination with aLA provoked protection from development of autochthonous tumors in transgenic murine models of breast cancer and inhibited growth of established 4T1 transplantable breast tumors in BALB/c mice. Methods: We completed accrual to a Phase I trial of recombinant human aLA with GMP-grade zymosan adjuvant in Montanide ISA 51 VG vehicle in 3 cohorts of subjects: Ia) patients with high-risk TNBC who have completed all standard treatment; Ib) patients with BRCA1, BRCA2, or PALB2 mutations who are undergoing risk-reducing mastectomies; and Ic) patients with TNBC who have residual cancer after primary chemo-immunotherapy and are receiving post-operative treatment with pembrolizumab +/- capecitabine. Three vaccinations were given once every 2 weeks. Events of Common Terminology Criteria for Adverse Events (CTCAE) Grade ≥ 2 are considered dose-limiting toxicities (DLTs). Blood was drawn prior to therapy as well as 14, 28, and 56 days after the first vaccination to assess cellular response using enzyme-linked immunosorbent spot (ELISPOT) assays of interferon-gamma and interleukin-17 production in response to aLA and for humoral response by enzyme-linked immunosorbent assay (ELISA). The breast tissue of participants in the Phase Ib cohort were or will be examined for occult lactational foci and inflammatory changes. Results: We vaccinated 26 patients in Cohort Ia, 4 in Cohort Ib, and 5 in Cohort Ic. CTCAE toxicity by dose level (DL) is summarized in Table 2 by grade for each study cohort. All adverse events (AEs) were injection site reactions, with ulceration and need for incisional drainage representing the Grade 3 DLT events. 26 of 35 patients (74%) across all cohorts met protocol specified definitions of an immune response based on ELISPOT assays that quantify frequencies of T cells producing IFNγ or IL-17 in response to recombinant aLA; these data included 4 of 6 subjects in Cohort Ia at DL1 and 10 of 15 subjects (67%) in all cohorts treated at DL1. Conclusions: DL1 is the maximum tolerated dose (MTD) by protocol definition, produced at worst Grade 1 toxicity in a total of 13 of 15 subjects, and produced an immune response in most patients, based on the criteria prospectively defined in the study protocol. DL1e was tolerable in 5 of 5 subjects but was not determined the MTD per our 3+3 trial design. Immune data for all subjects in the trial, including new data across all cohorts, are reported here and will inform the design of subsequent Phase II trials. Funding Source: Department of Defense (W81XWH-17-1-0592 and W81XWH-17-1-0593).

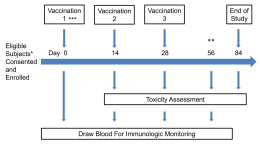
Key Eligibility Criteria And Study Design

All Cohorts
- Normal serum prolactin and no prolactin-raising medications
- No lactation within 6 months of study start
- Adequate major organ function
- Performance Status 0-1
- No other invasive cancer for five years
- No immunosuppressive therapy or steroids
- ≥ 4 weeks since prior chemotherapy or radiation (excluding capecitabine in cohort Ic)

TNBC Cohort (Ia)
- Pathologic Stage IIA-IIIC or residual disease following neo-adjuvant chemotherapy
- Completed all standard therapy
- Within 3 years of initial therapy for TNBC and not diagnosed while pregnant
- No evidence of recurrence or metastasis on restaging scans

Prevention Cohort (Ib)
- Have a high risk for developing TNBC, defined as: carrying a deleterious mutation in BRCA1, BRCA2, or PALB2
- Have scheduled risk reducing mastectomy at Cleveland Clinic Main Campus
- No current need for immunosuppression or systemic corticosteroid therapy
- No history of any invasive malignancy within the last 5 years

Pembrolizumab Cohort (Ic)
- Histologically proven invasive TNBC and not diagnosed while pregnant
- ≥ 1 month since last active therapy with chemotherapy (except capecitabine), radiation therapy, or surgery and at least 6 weeks of pembrolizumab therapy planned after the first dose of alpha-lactalbumin vaccine
- Residual invasive cancer after neoadjuvant chemotherapy + pembrolizumab



*Stage IIA-IIIC (cohort Ia) or residual disease following neo-adjuvant chemo- or chemo-immunotherapy (cohorts Ia and Ic)

**Subjects in the Ib cohort had prophylactic mastectomy between days 57 and 84

***Vaccination given during post-op pembrolizumab (cohort Ic)

Results

	TNBC Cohort Ia						Prevention Cohort Ib	Pembrolizumab Cohort Ic
	Number of Subjects (% of Total Subjects per Dose Level)							
	Dose Levels (mcg aLA/zymosan)							
	1 (10/10)	2b (10/10)	1e (10/20)	2 (old) (100/100)	2 (100/10)	3 (600/10)	2 (10/10)	3 (10/10)
Age								
30-39	-	1 (20)	1 (20)	-	1 (16.7)	-	2 (50)	1 (20)
40-49	1 (16.7)	2 (40)	3 (60)	-	-	1 (33.3)	1 (25)	1 (20)
50-59	1 (16.7)	-	-	1 (100)	2 (33.3)	1 (33.3)	1 (25)	1 (20)
60-69	4 (66.7)	1 (20)	-	-	2 (33.3)	-	-	2 (40)
70-79	-	1 (20)	1 (20)	-	1 (16.7)	1 (33.3)	-	-
Ethnicity								
Hispanic	-	-	-	-	-	-	-	1 (20)
Non-Hispanic	6 (100)	5 (100)	5 (100)	1 (100)	6 (100)	3 (100)	4 (100)	4 (80)
Race								
White	6 (100)	4 (80)	5 (100)	1 (100)	4 (66.7)	3 (100)	4 (100)	4 (80)
Black	-	-	-	-	1 (16.7)	-	-	-
South Asian	-	-	-	-	1 (16.7)	-	-	-
Multi Racial	-	1 (20)	-	-	-	-	-	-
Declined/ U/A	-	-	-	-	-	-	-	1 (20)

Table 1. Subject demographic summary. Numbers and percentages for all cohorts and dose levels are shown above for all 35 trial subjects.

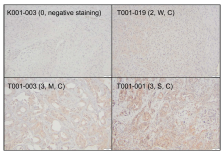


Figure 1. Immunohistochemistry (IHC) of primary tumors of study subjects detects a range of alpha-lactalbumin protein expression. Sections from subjects' primary tumors prior to vaccination were stained for the presence of alpha-lactalbumin protein and were scored by a clinical breast pathologist in a blinded manner according to the following criteria: **% Positivity** as 0 = <1% staining, 1 = 1-33% staining, 2 = 34-66% staining, 3 = 67-100% staining; **Average Intensity** as weak (W), moderate (M), or strong (S); **Localization** as cytoplasmic (C) or nuclear (N). Representative core biopsy sections exhibiting various aLa expression levels are shown to the right with subject codes and scores. Magnification is 200X; scale bars indicate 100 μm. IHC analysis and correlation with immune response and clinical outcomes is ongoing.

	TNBC Cohort Ia						Prevention Cohort Ib	Pembrolizumab Cohort Ic
	Dose Levels (mcg aLA/zymosan)							
	1 (10/10)	2b (10/10)	1e (10/20)	2 (old) (100/100)	2 (100/10)	3 (600/10)	(10/10)	3 (10/10)
Total Subjects Enrolled	6	5	5	1	6	3	4	5
Injection Site Reactions, Number of Subjects (%)								
Grade 1	6 (100)	3 (60)	5 (100)	-	5 (83)		4 (100)	3 (60)
Grade 2	-	1 (20)	-	-	-	1 (33)	-	-
Grade 3	-	1 (20)	-	1 (100)	1 (17)	2 (66)	-	2 (40)
Grade 4	-	-	-	-	-	-	-	-
Grade 5	-	-	-	-	-	-	-	-

Table 2. Prevalence of injection site reactions by study cohort, dose level, and CTCAE v5 grade. Toxicity consisted predominantly of injection site reactions characterized by erythema, swelling, lump formation, pruritus, and in severe cases ulceration with delayed healing. Injection site reactions accounted for all dose-limiting toxicity (DLT). No other DLTs were observed.

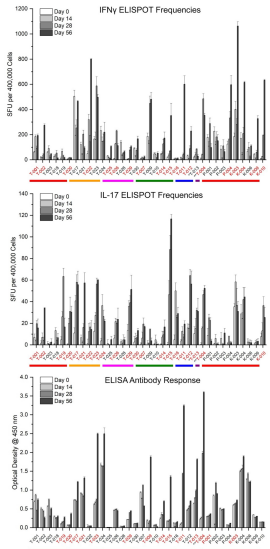


Figure 2. Individual immunologic data from all trial subjects (n=35) demonstrates a 74% response rate to the vaccine. In the figure to the left, ELISPOT frequencies are presented as spot forming units (SFU) per 400,000 PBMCs in culture minus background. ELISA antibody response is presented as the optical density at 450 nm of alpha-lactalbumin specific IgG wells minus background at a plasma dilution of 1:400. In all cases, background wells contained all components except antigen. All data are from individuals coded by subject ID. Subject ID prefix T = Phase Ia (TNBC); P = Phase Ib (prevention); K = Phase Ic (Keytruda/pembrolizumab). All error bars represent ±SD. Subjects in red font developed prospectively defined immune response which is defined for ELISPOT as ≥ 1 in 30,000 SFU or triple baseline (Day 0) at Day 56. Across the study, 74% of subjects demonstrated a positive response in the IFNγ and/or IL-17 ELISPOT assays. The ELISA is a correlative objective and subjects were deemed positive based on a substantial increase in signal over baseline (Day 0) by Day 56 concurrent with increasing antigen-specific IgG titers over time. *Third dose reduced to DL2 due to DLT in cohort. **No third dose administered due to DLT in subject.

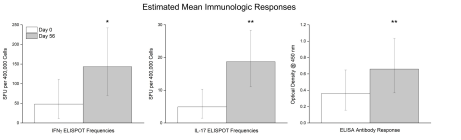


Figure 3. Estimated ELISPOT and ELISA means and statistical analysis of all trial subjects (n=35) demonstrate a significant immunologic response to the vaccine. The figure above shows the results of the statistical analysis of the immunologic data for all 35 subjects across all cohorts and dose levels. A significant increase over baseline (Day 0) was observed by Day 56 in the IFNγ ELISPOT (*P = 0.0001) and by Day 14 in the IL-17 ELISPOT (**P < 0.0001). The IgG response by ELISA in plasma at 1:400 dilution was also significant by Day 56 (**P < 0.0001). No significance was observed by dose level in any assay. The analysis includes data from all subjects across all three cohorts (Ia, Ib, and Ic) and all doses. The linear mixed model used can account for correlations between measurements over time within the same patient. Due to right skewness, raw data was transformed to square root scale and estimated were back-transformed to raw scale for reporting. Dose Level 2 (old) is excluded from analysis due to only one subject treated. P-values were calculated by likelihood ratio test. Batch correction was used in all calculations. Error bars represent 95% confidence intervals. *P = 0.0003 and **P < 0.0001 with Dunnett's adjustment applied.

Discussion, Conclusions, and Plans

- **Among the doses studied, Dose Level 1 (DL1) is the maximum tolerated dose (MTD).**
  - DL1 produced no greater than Grade 1 AEs in all subjects tested except 2 of the 5 in the pembrolizumab cohort.
  - Dose Level 1e (DL1e) was tolerated in 5 of 5 subjects tested and may be further explored for Phase II.
  - All dose-limiting toxicities (DLTs) were injection site reactions; no other DLTs were observed.
- **DL1 is a usable optimal immunologic dose based on toxicity and IFNγ and IL-17 ELISPOT responses in subjects not concurrently treated with pembrolizumab. Toxicity at DL1 with concurrent pembrolizumab might be acceptable for high risk cancer patients.**
- **IFNγ and/or IL-17 ELISPOT cellular immune responses were seen in the majority (74%) of patients.**[1]
  - IFNγ and/or IL-17 ELISPOT cellular immune responses were seen at all dose levels, including DL1.[1]
  - Statistically significant increases over baseline with time were observed in ELISPOT assays for IFNγ and IL-17, and in ELISA.
  - No statistically significant dose response was observed in any assay.
- Immunohistochemistry (IHC) of subjects' primary tumors for alpha-lactalbumin protein revealed a range of expression from absent to strong. Analysis and correlation to immune response and clinical outcomes is ongoing.
- Consenting subjects will be followed for five years after completing the study.
- **All primary study endpoints were met and these results and follow-up data will inform the design of Phase II studies.**

[1]The clinical protocol defines an antigen-specific immune response as the post-treatment development of ≥ 1/30,000 IFNγ-secreting (Type 1) or IL-17 secreting (Type 17) T cells in the peripheral blood monocytes in response to α-lactalbumin. If this level of response is present prior to therapy, a 3-fold increase of IFNγ-secreting (Type 1) or IL-17 secreting (Type 17) T cells in the peripheral blood monocytes will be an immunologic response.

Cleveland Clinic

Case Western Reserve University | Case Comprehensive Cancer Center

Contact
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Conflict of Interest Statement
The vaccine technology discussed in the abstract and poster has been licensed to Arixa Biosciences, Inc. (San Jose, CA). JMJ is an inventor on issued and pending patents related to the vaccine technology presented here and may earn royalties for such if the vaccine becomes commercially successful. In addition, JMJ have received equity in Arixa Biosciences, Inc. in the form of stock options. The abstract and poster were prepared without any input or coercion whatsoever from the licensee.