

Mix it up

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THE GLUTEN-FREE KINGDOM

A PRIMER ON GLUTEN-FREE BREAD

A decade ago gluten-free breads were made by only a few companies and consisted mainly of starchy and fiber-less ingredients. The bread had a reputation for being heavy and dry. Most loaves were not edible right out of the package and had to be toasted. Consumers usually discovered this fact on their own, after trial and error that was time consuming and costly.

Although packaged gluten-free bread has improved dramatically, it still doesn't behave exactly like gluten-containing bread. Generally preservatives aren't used, which explains why most gluten-free bread available in supermarkets is either frozen or vacuum packed.

Here are answers to questions that often come up regarding gluten-free bread.

- **Can it sit on the counter like wheat bread?** Generally gluten-free bread does not last on the counter and will quickly become moldy. Some bread makers are attempting to address this problem with newer products, but in most cases you need to take the slices you are planning to use from the loaf and freeze the rest. Most bread can be stored in the freezer for 4 to 6 months.
- **Should it be stored in the refrigerator?** Storing gluten-free bread in the refrigerator can lead to dry and stale bread.
- **How do you get the slices apart?** Some gluten-free bread freezes hard, making it difficult to separate the slices. If you let the bread sit on the counter for a short time, though, you can usually get the slices apart. Return the rest of the bread to the freezer.
- **Can you eat it from the bag?** Many gluten-free breads taste much better toasted. This is another issue bread companies are beginning to address. Kinnikinnick, Glutino and Schär all have products that either the company or consumers say don't need to be toasted.

—Jennifer Harris

CELIAC DRUG MOVES INTO TRIAL STAGE



A drug to treat celiac disease moved closer to reality with the announcement that it will be tested in a large clinical trial later this year.

Innovate Biopharmaceuticals has announced that a compound known as larazotide acetate, or INN-202, will be tested in a Phase 3 clinical trial, the first time a celiac disease drug has gotten this far in the approval process.

Larazotide acetate has the potential to become the first approved medicine to treat celiac disease and has been granted “Fast Track” designation from the U.S. Food and Drug Administration (FDA).

The medicine is not intended to allow those with celiac disease to knowingly consume foods containing gluten. Instead it works with the gluten-free diet to prevent so-called “leaky gut” syndrome in cases of incidental cross-contamination.

Larazotide acetate belongs to a class of drugs called tight junction regulators. Tight junctions, which are located in the bowel, should remain closed except to shed dead cells. However, in patients with celiac disease, the presence of gluten causes the tight junctions to remain open. This starts an inflammatory cascade within the bowel that eventually destroys the absorbing lining, called the intestinal villa.

Early research suggests larazotide acetate may help keep the tight junctions

closed when taken prior to a meal, thus reducing the inflammatory process in response to gluten.

In the Phase 3 clinical trial, the drug will be given to large groups of people to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow it to be used safely. If Phase 3 is completed successfully, Innovate can request approval from the FDA for marketing the drug.

According to the FDA the length of the study in this phase can last anywhere from one year to four years. If the trial shows that the drug is safe and effective for its intended use, Innovate can apply for marketing approval. From that point the FDA has 6 to 10 months to make a decision whether to approve the drug.

“There is a huge demand for adjunctive therapies from the celiac patient community, and I am happy to see larazotide acetate moving ahead with what will be the first Phase 3 trials ever conducted in celiac disease,” said Daniel A. Leffler, M.D., director of research at the Celiac Center at Beth Israel Deaconess Medical Center in Boston.

Alba Therapeutics, which conducted the initial research and development of the drug, previously known as AT-101, recently licensed the additional clinical testing and future distribution rights to Innovate.

—Michael Savett