DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

TRANSMITTED VIA FACSIMILE

SEP -5 2000

Synsorb Biotech Inc.
John J. Frey, Ph.D.
Vice President
Clinical and Regulatory Affairs

c/o Arthur Y. Tsien
Olsson, Frank and Weeda, P.C.
Attorneys at Law
Suite 400
1400 Sixteenth Street, N.W.
Washington, D.C. 20036-2220

RE: IND #[ ]
SYNSORB Pk
MACMIS ID # 9264

Dear Mr. Tsien:

As a part of the Division of Drug Marketing, Advertising, and Communications' (DDMAC) routine surveillance, we have reviewed two press releases on the website for Synsorb Biotech Inc.'s (SBI) product SYNSORB Pk[1]. In the two press releases, SBI promotes SYNSORB Pk as safe or effective for the prevention of progression to Hemolytic Uremic Syndrome (HUS) in children infected by *E. coli*. We find the press releases in violation of the Federal Food, Drug, and Cosmetic Act and its applicable regulations. Specifically, we object to the following:

Pre-Approval Promotion

SYNSORB Pk is an investigational new drug that has not been approved by the Food and Drug Administration as being safe or effective. SBI has promoted SYNSORB Pk as safe or effective prior to approval for the treatment of HUS in children infected by *E.coli*.

For example, in the July 12, 2000 press release, SBI reported results on their planned interim analysis, which showed a limited trend toward efficacy and did not successfully meet the defined

[1] Press releases dated July 12, 2000 and August 3, 2000, from the Synsorb Biotech Inc. website: http://www.synsorb.com (August 4, 2000).

protocol objectives. However, SBI also provided misleading statements and conclusions from an unplanned subgroup analysis, which included:

- *Approximately one third of the patients were treated within 2 days of the onset of their symptoms and data from this sub-group of 152 patients demonstrated a statistically significant ($p<0.05$) lower rate of HUS for SYNSORB Pk compared to placebo.*
- *We are very excited to see statistically significant clinical data for SYNSORB Pk in this sub-group of children.*
- *The drug appears to offer substantial benefit to patients when treatment is started during the first 2 days of their symptoms.*
- *Given the findings in this subgroup, SYNSORB has determined that it would not be appropriate to continue recruiting patients in the current trial until the Company has engaged with the regulatory authorities to discuss options for concluding the program.*

These misleading statements regarding the significance of the unplanned sub-group analysis are reiterated in a press release dated August 3, 2000, which include:

- *We have recently reported interim data showing that SYNSORB Pk can reduce the progression of HUS in children when administered within the first 2 days of diarrhea symptoms.*
- *Outcomes of an interim analysis of the SYNSORB Pk Phase III data announced previously revealed that when administered within 48 hours of symptoms, the product reduced the progression to HUS in children by 59%. As a result, SYNSORB is engaging with the regulatory authorities to obtain feedback regarding the best strategy to successfully complete the development of SYNSORB Pk.*

Failure to Present Material Facts

In addition, SBI presents misleading statements that fail to disclose facts that are material in light of representations made about SYNSORB Pk. SBI presents the results from the Phase III trial interim analysis that revealed that in 526 children treated within 5 days of the onset of symptoms, there was a limited trend toward efficacy, and the trial failed to meet designed protocol objectives. However, SBI then presented a sub-group analysis, which evaluated 152 children treated within two days of the onset of symptoms. SBI concluded that there was a statistically significant ($p<0.05$) lower rate of HUS for SYNSORB Pk compared to placebo. This presentation is misleading because the sub-group analysis was not part of the original Phase III study design, did not demonstrate a definitive finding, and may have occurred purely by chance. SBI implies that the sub-group analysis showed significant findings to complete the development of SYNSORB Pk when in fact, in discussion with FDA, it was determined that appropriate studies are needed to determine safety or efficacy.

Requested Action

We request that SBI immediately cease dissemination of materials and activities that contain these and similar representations, and conclusions concerning the safety or efficacy of SYNSORB Pk. In addition, we request that SBI submit a written response on or before September 12, 2000 describing its intent and plans to comply with the above. The response should include a list of materials discontinued and the date on which these materials were discontinued.

You should direct your response to the undersigned by facsimile by at (301) 594-6759, or to the Food and Drug Administration, Division of Drug Marketing, Advertising, and Communications, HFD-42, Rm 17-B-20, 5600 Fishers Lane, Rockville, MD 20857. We remind you that only written communications are considered official.

In all future correspondence regarding this particular matter, please refer to MACMIS ID # 9264 in addition to the IND number.

Sincerely,

/S/

James R. Rogers, Pharm.D.
Regulatory Review Officer
Division of Drug Marketing,
Advertising, and Communications

te delayed minimum 15 minutes)...

08/03/00 SYNSORB Provides SYNSORB Pk for Treating E. coli Patients...
07/14/00 SYNSORB to Host Dial-In Conference Call for Investors...
07/12/00 SYNSORB Announces Outcome of SYNSORB Pk Interim Analysis...

SYNSORB Overview
- Please make a selection -
SYNSORB OVERVIEW
Updated July 28, 2000
Click in the drop down box above for more subsections

SYNSORB

COMPANY OVERVIEW

SYNSORB Biotech Inc. is a publicly traded Canadian pharamceutical company dedicated to drug development and manufacturing. The Company has two late-stage products, both of which are based on SYNSORB's proprietary carbohydrate chemistry platform technology, and both of which have been granted "Fast Track Designation" from the USFDA.

Headquartered in Calgary, SYNSORB currently has two such carbohydrate products in late stage clinical development, SYNSORB Pk® and SYNSORB Cd®. SYNSORB Pk® is in Phase III clinical trials and is designed to prevent the progression to Hemolytic Uremic Syndrome (HUS) in children who have contracted verotoxigenic *E. coli* (VTEC) infections (including *E. coli* O157:H7). SYNSORB Cd® will commence Phase III trials in the first part of 2000, and is designed to treat recurrent *Clostridium difficile* antibiotic-associated diarrhea (CDAD), a common hospital acquired infection.

SYNSORB has built a cGMP-compliant manufacturing facility that has the capacity to meet or exceed the expected global demand for the Company's products. A pipeline of future products is accessible through SYNSORB's carbohybrid program.

COMPANY BACKGROUND

SYNSORB Biotech Inc. was incorporated on February 14, 1994 in Alberta. The SYNSORB technologies are based on the discoveries and work done by the Chemistry Department at the University of Alberta, and were subsequently transferred to the Alberta Research Council. SYNSORB licensed the technologies from the ARC in May 1994. The Company became public in October 1994.

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nge: .400 Volume: 117450 Trades: 155 Open: 4.300 Quote last updated: Aug 04, 10:40am -- (

08/03/00 SYNSORB Provides SYNSORB Pk for Treating E. coli Patients...
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07/12/00 SYNSORB Announces Outcome of SYNSORB Pk Interim Analysis...

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SYNSORB Overview

WHAT'S NEW !

Updated July 17, 2000

WHAT'S NEW AT SYNSORB

Wednesday July 12, 2000

SYNSORB announced the outcome of an interim analysis of the SYNSORB Pk® Phase III clinical trial data.

SYNSORB discovered that when administered early (within 2 days from the onset of symptoms), SYNSORB Pk® demonstrates a statistically significant reduction in the rate of HUS compared to placebo. This information was obtained through a subset analysis of patients, even though it was also learned that the trial's objectives were not met in the overall patient population.

"We are very excited to see statistically significant clinical data for SYNSORB Pk® in this sub-group of children," said Dr. David Cox, President and CEO of SYNSORB. "The drug appears to offer substantial benefit to patients when treatment is started during the first 2 days of their symptoms. Given these results, we clearly need to consult with the regulatory authorities and other stakeholders to determine how we can best capitalize on this valuable data and take full advantage of this opportunity."

To read the July 12th news release, Click Here

Thursday May 25, 2000

In response to an *E. coli* outbreak in Walkerton, ON that reportedly sickened 1000 people, SYNSORB received approval from Health Canada to ship an emergency supply of SYNSORB Pk under compassionate use. To read the news release **Click Here**

Since the product was shipped under compassionate use and not administered in a clinical trial setting, the Company is unable to release any 'results'. The feedback received thus far has been positive and SYNSORB remains ready and willing to supply further help to Walkerton or other regions should the need arise.

SYNSORB's 1999 Annual Report

SYNSORB's 1999 Annual Report is available on-line in PDF format. To view a copy of this report, **Click Here**, or request to receive a copy of the report via mail with our document request form by **Clicking Here**

SYNSORB Launches Phase III trials for SYNSORB Cd(R)

April 3, 2000

SYNSORB today announced that the SYNSORB Cd(R) Phase III clinical trials have been officially launched with the enrollment of the first patient. SYNSORB Cd(R) is designed to prevent recurrent *Clostridium difficile* antibiotic-associated diarrhea (CDAD), and is the Company's second product to enter Phase III trials, the final stage of clinical testing prior to filing a New Drug Application (NDA).

"Starting the Phase III trials earlier than anticipated clearly demonstrates the effectiveness of our focused strategy and our dedication to the expeditious completion of these trials which will form the basis for our worldwide regulatory submissions to market SYNSORB Cd(R)," said Dr. David Cox, President and CEO of SYNSORB. "This accomplishment moves SYNSORB closer to achieving our goal of developing the first treatment for recurrent CDAD."

SYNSORB is conducting two identical Phase III clinical trials for SYNSORB Cd (R). Each trial will target 60 sites, one with sites strictly in the US, and one with sites in the US, Canada and possibly Europe. Two different dose sizes of SYNSORB Cd(R), 16g per day and 24g per day, will be co-administered with metronidazole and tested for efficacy against placebo. The primary endpoint is a clinically significant reduction in the rate of Recurrent CDAD. The Company intends to conduct the Phase III trials aggressively and anticipates filing the application for marketing approval in 2002.

To read the full release, **Click Here**

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Stock Quote courtesy of StockWatch

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Symbol: SYB Exchange: TSE Bid: 4.320 Ask: 4.450 Last: 4.400 Change: .400 Volume: 11

Products & Clinical Trials

- Please make a selection -

PRODUCTS & CLINICAL TRIALS

Updated June 01, 2000

PRODUCTS & CLINICAL TRIALS

SYNSORB has two Phase III products undergoing clinical development. Both products are based on the same platform technology, consisting of synthetically produced carbohydrates (sugars) that are designed to bind specifically to targeted toxins. These carbohydrates (known as trisaccharides) are stabilized by being chemically linked to an inert silica-like substrate. This creates an insoluble molecular complex which, when orally administered, is quickly delivered to the gut.

Once in the gut, the SYNSORB complex is designed to bind and immobilize potentially damaging bacterial toxin, which are then excreted normally from the body. **SYNSORB Pk®** and **SYNSORB Cd®** are both based on this platform technology.

SYNSORB Biotech Inc. encourages physicians and research centres that may be interested in becoming involved in our ongoing clinical trials to contact us, either through this website or via other means. We, however, graciously decline to accept proposals from study brokers for participation.

SYNSORB is accepting inquiries from interested investigators, and we thank you for your interest in our clinical programs.

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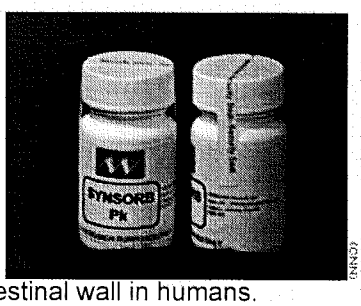
SYNSORB PK

Updated May 23, 2000

SYNSORB Pk®

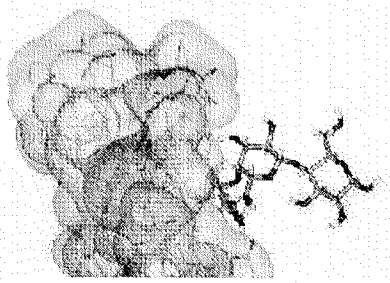


Infections caused by the bacterium *E. coli* O157:H7 are recognized as one of the fastest growing foodborne infectious diseases in the world. *Escherichia coli* is a species of bacteria normally found in the intestinal flora of humans and some animal species. Verotoxigenic *E. coli* or "VTEC" (including O157:H7), are virulent strains of the bacterium which produces toxins that bind to the sugar based receptors on the intestinal wall in humans. Sometimes referred to as "hamburger disease", VTEC sources include undercooked contaminated ground meat as well as other sources such as dairy products prepared with unpasteurized milk; vegetables; fruit; ground water; or person-to-person contact.

Once ingested, the toxins pass through the stomach and small bowel and become attached to the wall of the large intestine. This can cause an inflammatory response with the formation of shallow ulcers in the lining of the terminal ileum and colon, and result in diarrhea. Early symptoms include bloody diarrhea, lethargy and sometimes fever. In approximately 10-20% of infected patients, the toxins may enter the blood through the ulcerative lining of the intestines. Circulating toxins then bind to certain carbohydrate receptors which are concentrated in red blood cells and the kidneys. Young children and the elderly are most at risk of complications with up to 20% of children five and under developing Hemolytic Uremic Syndrome (HUS), a severe and sometimes fatal kidney disease. Patients who survive can face a lifetime of dialysis and other serious complications at great cost to their quality of life and to the health care system.

****Click here to see a chart on how Pk works in the body****

The image below is a depiction of how the synthetic oligosaccharide on SYNSORB Pk® imitates the carbohydrate receptors that the toxins bind to on human red blood cells and kidney cells. The SYNSORB Pk® / toxin complex is then excreted normally as waste.



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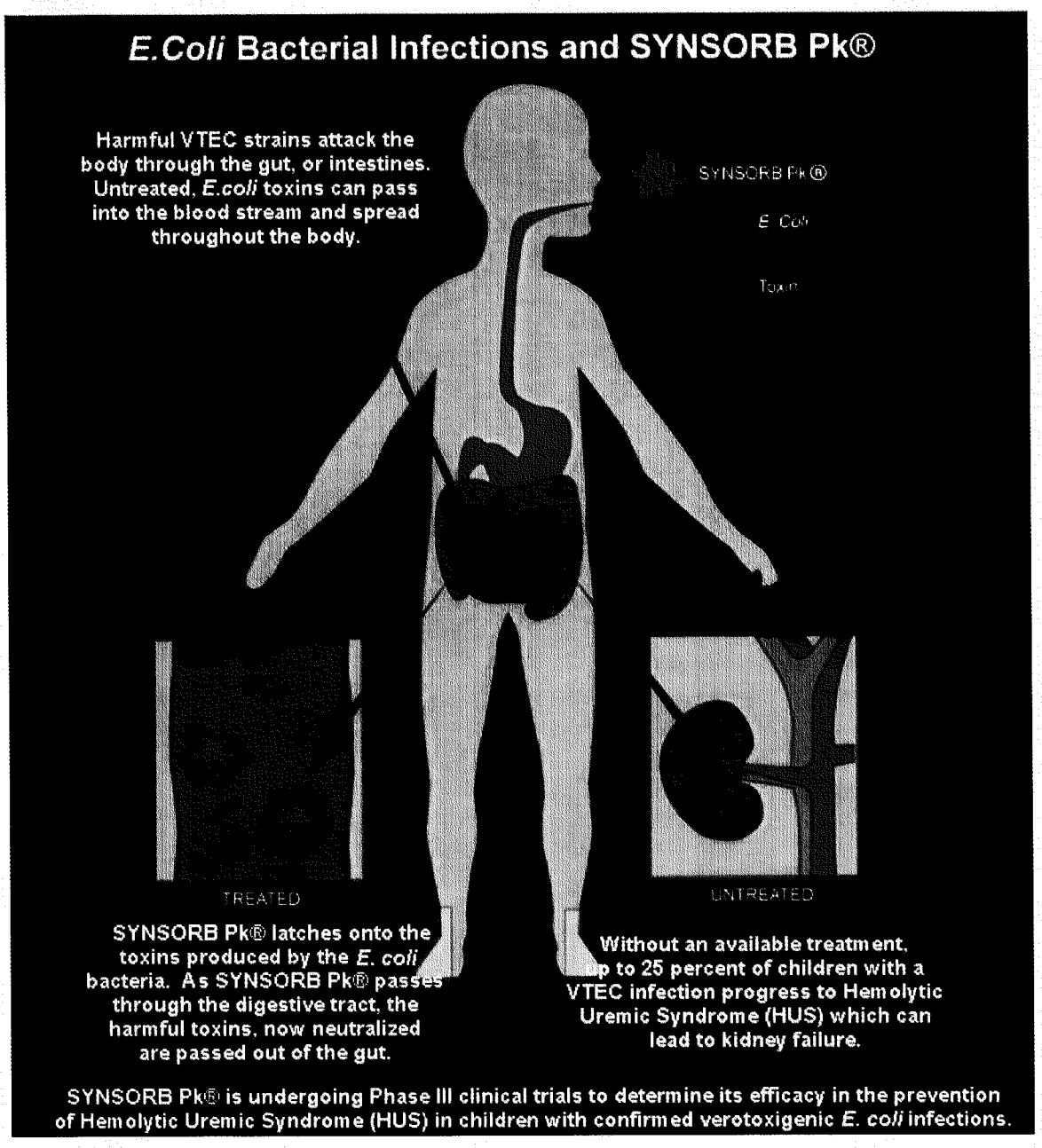
E.Coli Bacterial Infections and SYNSORB Pk®
Harmful VTEC strains attack the body through the gut, or intestines. Untreated, E.coli toxins can pass into the blood stream and spread throughout the body.
SYNSORB Pk®
E Coli
Toxin
TREATED
UNTREATED
SYNSORB Pk® latches onto the toxins produced by the E. coli bacteria. As SYNSORB Pk® passes through the digestive tract, the harmful toxins, now neutralized are passed out of the gut.
Without an available treatment, up to 25 percent of children with a VTEC infection progress to Hemolytic Uremic Syndrome (HUS) which can lead to kidney failure.
SYNSORB Pk® is undergoing Phase III clinical trials to determine its efficacy in the prevention of Hemolytic Uremic Syndrome (HUS) in children with confirmed verotoxigenic E. coli infections.

SYNSORB Provides SYNSORB Pk for Treating E. coli Patients

Released 08-03-2000

(Press Control-P to Print this page)
Click to switch news release to black and white.

Calgary, August 3, 2000 --- SYNSORB Biotech Inc. ("SYNSORB") (TSE: SYB, NASDAQ: SYBB), today announced that it has received authorization from the United States Food and Drug Administration (FDA) to provide emergency doses of SYNSORB Pk® to the Children's Hospital of Wisconsin, located in Milwaukee, Wisconsin. The drug will be used to treat children infected with *E. coli* under the care of Dr. Kelly Henrickson, an Associate Professor of Pediatrics and Microbiology at the University of Wisconsin, and Pediatric Infectious Disease Specialist at the Children's Hospital of Wisconsin.

"SYNSORB is fully committed to assisting and supporting Dr. Henrickson and other physicians in Milwaukee by providing SYNSORB Pk®," said Dr. David Cox, President and CEO of SYNSORB. "We have recently reported interim data showing that SYNSORB Pk® can reduce the progression to Hemolytic Uremic Syndrome (HUS) in children when administered within the first 2 days of diarrhea symptoms. Since there is no approved therapy for this disease, we are pleased to offer SYNSORB Pk® along with our support for the Milwaukee families stricken by this dreadful infection."

There is no approved therapy currently available for patients suffering from verotoxigenic *E. coli* (VTEC) infections. The compassionate use shipments of SYNSORB Pk® were authorized by the FDA under emergency Investigational New Drug (IND) provisions. This emergency IND permits Dr. Henrickson to administer the product to patients who are confirmed with *E. coli* infections. Due to the 2 to 10 day incubation period of *E. coli* , physicians and hospitals continue to report new patients suffering from symptoms of the infection. A shipment of 5 treatments has already been sent under compassionate use, and additional supplies can be sent upon request.

"In outbreak situations like this, it is heartbreaking to watch patients, especially children, suffer without being able to offer any treatment," noted Dr. Kelly Henrickson. "I am very pleased to have access to doses of SYNSORB Pk® that can be administered to patients during this severe outbreak."

SYNSORB Pk® is a drug designed to prevent serious complications associated with VTEC infections (including *E. coli* O157:H7). Outcomes from an interim analysis of the SYNSORB Pk® Phase III data announced previously revealed that when administered within 48 hours of symptoms, the product reduced the progression to HUS in children by 59%. As a result, SYNSORB is engaging with the regulatory authorities to obtain feedback regarding the best strategy to successfully complete development of SYNSORB Pk®.

SYNSORB Pk® has been granted Fast Track Product designation by the FDA, which is only given to those products that are designed to treat serious, life-threatening conditions for which there is no satisfactory treatment.

VTEC is recognized as the fastest growing foodborne infectious disease in the world and is estimated to cause approximately 110,000 infections each year in the US. Sources of the infection include contaminated meat, fruit and vegetables, unpasteurized juice and milk, contaminated ground water, contaminated swimming pool water, and direct contact with infected people or animals. The disease is a leading cause of both acute and chronic renal insufficiency in children, and there is currently no treatment whatsoever for this disease, which can be fatal.

SYNSORB is a Canadian-based pharmaceutical company dedicated to drug development and manufacturing. In addition to SYNSORB Pk®, the Company has a second Phase III product, SYNSORB Cd® which has also been granted "Fast Track" designation by the FDA. SYNSORB Cd® is a potential treatment for recurrent *C. difficile* antibiotic associated diarrhea (CDAD), a common hospital acquired infection. SYNSORB has built a cGMP-compliant manufacturing facility that has the capacity to meet or exceed the expected global demand for the Company's products. A pipeline of future products is accessible through SYNSORB's carbohybrid program.

Shares of SYNSORB Biotech Inc. trade on the Toronto Stock Exchange in Canada (symbol "SYB") and on NASDAQ in the United States (ticker "SYBB")..

This release contains certain forward-looking statements which involve known and unknown risks, delays, uncertainties and other factors not under the Company's control which may cause actual results, performance or achievements of the Company to be materially different from the results, performance or other expectations implied by these forward-looking statements. These factors include results of current or pending clinical trials, actions by the FDA/HPB and those factors detailed in the Company's registration statement on Form 20 F filed with the Securities and Exchange Commission.

For further information please contact:

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SYNSORB Announces Outcome of SYNSORB Pk Interim Analysis

Released 07-12-2000

(Press Control-P to Print this page)
Click to switch news release to black and white.

Calgary, July 12, 2000 --- SYNSORB Biotech Inc. ("SYNSORB") (TSE: SYB, NASDAQ: SYBB), today announced the outcome of an interim analysis of the SYNSORB Pk® Phase III trial, which was investigating the clinical efficacy of SYNSORB Pk® in preventing the progression to Hemolytic Uremic Syndrome (HUS) in children suffering from *E. coli* infections (including *E. coli* O157:H7). In the overall patient population of 526 children treated within 5 days of the onset of symptoms, the data showed a limited trend toward efficacy, and did not successfully meet the defined protocol objectives.

However, approximately one third of the patients were treated within 2 days of the onset of their symptoms and data from this sub-group of 152 patients demonstrated a statistically significant ($p<0.05$) lower rate of HUS for SYNSORB Pk® compared to placebo. The rate of HUS was 7% for patients in the SYNSORB Pk® group compared to 17% for the placebo group. The risk reduction of developing HUS for SYNSORB Pk® relative to placebo was 59%.

"We are very excited to see statistically significant clinical data for SYNSORB Pk® in this sub-group of children," said Dr. David Cox, President and CEO of SYNSORB. "The drug appears to offer substantial benefit to patients when treatment is started during the first 2 days of their symptoms. Given these results, we clearly need to consult with the regulatory authorities and other stakeholders to determine how we can best capitalize on this valuable data and take full advantage of this opportunity."

An independent assessment of the interim results was performed by a Data and Safety Monitoring Committee (DSMC), comprised of third-party external reviewers. The DSMC confirmed the safety of SYNSORB Pk® and concluded that there were no ethical or scientific reasons which would suggest discontinuing the trial. However, given the findings in the sub-group, SYNSORB has determined that it would not be appropriate to continue recruiting patients in the current trial until the Company has engaged with the regulatory authorities to discuss options for concluding the program.

If further recruitment of patients into the trial is deemed to be necessary, the Company may seek third party financial support. SYNSORB has consulted with existing marketing partners for SYNSORB Pk®, Takeda Chemical Industries Ltd., Paladin Labs, Inc. and Tramedico International BV, all of whom agree with this strategy to determine the next course of action.

Verotoxigenic *E. coli* (including *E. coli* O157:H7) is recognized as the fastest growing foodborne infectious disease in the world and is estimated to cause approximately 110,000 infections each year in the US. Sources of the infection include contaminated meat, fruit and vegetables, unpasteurized juice and milk, contaminated ground water, contaminated swimming pool water, and direct contact with infected people or animals. The disease is a leading cause of both acute and chronic renal insufficiency in children, and there is currently no treatment whatsoever for this disease, which can be fatal.

SYNSORB Pk® is a drug designed to prevent serious complications associated with verotoxigenic *E. coli* (VTEC) infections (including *E. coli* O157:H7). A proportion of patients who become infected with *E. coli* will go on to develop Hemolytic Uremic Syndrome (HUS), a severe and sometimes fatal kidney disease. Children and the elderly are most likely at risk of developing HUS, which can lead to a lifetime of dialysis and other serious complications. SYNSORB Pk® has been granted Fast Track Product designation by the US FDA, which is only given to those products that are designed to treat serious, life-threatening conditions for which there is no satisfactory treatment.

SYNSORB is a Canadian-based pharmaceutical company dedicated to drug development and manufacturing. In addition to SYNSORB Pk®, the Company has a second Phase III product, SYNSORB Cd® which has also been granted "Fast Track" designation by the FDA. SYNSORB Cd® is a potential treatment for recurrent *C. difficile* antibiotic associated diarrhea (CDAD), a common hospital acquired infection. SYNSORB has built a cGMP-compliant manufacturing facility that has the capacity to meet or exceed the expected global demand for the Company's products. A pipeline of future products is accessible through SYNSORB's carbohybrid program.

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