EPITORAL •

COMPANY "VITAL STATS"

San Diego, California Founded 2022 Spinoff of Epitome Pharmaceuticals Ltd, now closed. https://epitomeantiviral.com

MANAGEMENT TEAM

Paul T. Wegener (attending conference) pwegener@epitomeantiviral.com

BOARD MEMBERS & AFFILIATIONS

Saverio Bettuzzi, PhD. Emeritus Professor, University of Parma Dr. Yukihiko Hara, PhD. Former Director: Food Research Laboratory, Mitsui Norin Co. Ltd Dr. Hara and colleagues produce Theaphenon E

since the production of Polyphenon E was terminated in 2017.

COLLABORATIONS/PARTNERS OR OPPORTUNITIES TO PARTNER

None yet; would you like to join in?

CONTACT

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INHALATION THERAPY WITH GREEN TEA EXTRACT Inhibits NF-kB, Reduces Lung Inflammation

Green tea extract (GTE) is a powerful effector which is widely studied; there are 22,000 papers listed in PubMed since 1975, with over 1,400 in 2024. It has antioxidant, anti-viral and anti-bacterial activity, binds many proteins and improves intestinal microflora.

GTE inhibits all viruses tested including SARS-CoV-2 ^{1–3}, influenza A & B⁴, papilloma virus, rotavirus and enterovirus,⁵ at concentrations of 10 PPM. ⁶ These results were obtained in vitro and in vivo; tests in mice showed survival after doses of virus lethal in controls. ⁷ Animal viruses Pseudorabies virus, bovine herpes virus 1, porcine transmissible gastroenteritis virus and porcine epidemic diarrhea virus are also inactivated in vitro. ⁶ GTE inhibited influenza infection in pigs when delivered as a mist at 300 PPM for 20 seconds every half hour and in their drinking water. Control animals had a 4x increase in H antigen, those inhaling and drinking GTE had far less. ^{6,8}

GTE and its principal component EGCg inhibit NF-kB activation in vitro and in animal models in dozens of studies. ^{9–13} EGCG, the principal component of GTE, binds the NF-kB-p65 protein covalently and prevents it from binding DNA .¹⁴ NF-kB activation is the main trigger of inflammation by the innate immune system, see diagram below from ¹⁵.



Respiratory failure requiring ventilation affects 455 per 100,000 people a year in the US. The death rate is 23% and survivors have many morbidities; treatment cost was \$181 billion in 2017.¹⁶ The many manifestations of respiratory failure, called ARDS, ALI, ARF, and SARS, share commonalities. The SARS-CoV-2 pandemic gave new impetus to research in this field. A striking finding of Rouhani et al at, 2021, at University of Chicago was that in patients who had died of SARS, the cytokines IL-6 and CCL2 of the cytokine storm were being generated by the lung type II pneumocytes, not the circulating immune cells.¹⁷ These cells have activated Nf-kB, the classic driver of inflammation.

In 2020 Dr. Saverio Bettuzzi, Professor Emeritus of University of Parma Medical School, and colleagues tested inhalation and oral therapy with GTE in 10 COVID-positive subjects; half were over 50 years old and had CT-confirmed lung involvement. Patients, including all lung-involved, recovered at median of 9 days, range 7 – 15 days and 7 of 10 had a negative COVID test. The result was highly significant compared to the neighboring province, where the mean time to a negative test was 21 days, P < 0.003. All subjects completed two weeks of treatment with no adverse events at all.¹⁸

Intellectual property rights are very strong. The NDA for the green tea extract Polyphenon E (sinecatechin) was FDA-approved as the active ingredient in Veregen ointment to treat genital warts in 2006. The US FDA defines a botanical API as the product of a cGMP process, not chemically.

The process begins with the Good Agricultural Process on the farms growing the tea and ends with the packaged product; all these steps are specific and proprietary.¹⁹ There are no botanical generics. Every competitor must duplicate the pre-clinical toxicology and Phase I trials, which cost \$60 million and took 7 years.



SUMMARY

SUMMARY OF COVID-19 TRIAL 2020

10 subjects with positive COVID test received:

Theaphenon E green tea extract, 74% EGCG, in 0.3% solution by inhalation by nebulizer, 5 ml per session q.d. (daily dose of 2.2 mg EGCG)

Theaphenon E green tea extract capsules, 210 mg EGCg per capsule, four capsules per day with meals and at bedtime.(daily dose of 840 mg EGCG)

Subject #	Age	CT lung SARS	Days of treatment	Result swab S2	Initial IL- 6 pg/ml	Final IL- 6 pg/ml
6	27		9	negative	7.82	4.34
8	28		6	negative	12.75	12.75
10	38		6	positive	17.37	194.05
5	47		13	negative	8.25	2.87
3	50		6	positive	6.00	24.19
4	53	10 - 15%	7	negative	69.08	9.90
7	55		5	positive*	184.95	3.00
9	66	40%	10	negative	124.42	14.76
2	73	10 - 15%	6	negative	55.50	5.21
1	74	10 - 15%	6	negative	26.03	1.50
Median days			6.0			
Highest			13	bold if > 10		
Lowest			5	 Very low viral load 		

Results: (sorted by age)

We are looking for a qualified partner to develop this medication.

References on separate sheet, please ask.